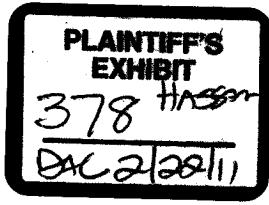


# EXHIBIT 14

GLOBAL AGREEMENT



GLOBAL AGREEMENT

AMONG

PFIZER INC.,

MONSANTO COMPANY

AND

G.D. SEARLE & CO.

(Celecoxib and Second Generation)

February 18, 1998

GLOBAL AGREEMENT  
(Celecoxib and Second Generation)

This Agreement, dated as of February 18, 1998 (the "Effective Date"), among PFIZER INC. and CP Pharmaceuticals International C.V. (collectively, "PFIZER"), MONSANTO COMPANY ("MONSANTO"), G.D. SEARLE & Co. ("SEARLE") and an Affiliate to be named.

WHEREAS, SEARLE is a wholly-owned subsidiary of Monsanto.

NOW, THEREFORE, the parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

The following capitalized terms shall have the following meanings:

- 1.1. "Act" means the United States Food, Drug and Cosmetic Act, as amended, and the regulations thereunder.
- 1.2. "Affiliate" means any entity directly or indirectly controlled by, able to control or under common control with a party to this Agreement, but only for so long as such control shall continue. For purposes of this definition, "control" means possession, direct or indirect, of the power to direct or cause direction of the management and policies of an entity. Notwithstanding the foregoing, G. D. SEARLE (Philippines) Inc., SEARLE Pakistan (Private) Limited, and SEARLE (India) Limited shall be deemed to be Affiliates of SEARLE for purposes of this Agreement. References to "party" and "PFIZER" shall include PFIZER's Affiliates, as appropriate, and references to "party", "MONSANTO" and "SEARLE" shall include MONSANTO's and SEARLE's Affiliates, as appropriate. References to "parties" shall mean PFIZER, and

its Affiliates, as appropriate, on the one hand and MONSANTO and SEARLE, and their Affiliates, as appropriate on the other hand.

1.3. "Agreements" means this Agreement, the U.S. Agreements, the International Collaboration Agreements and the International License Agreements.

1.4. "Business Day" means a day that is not a Saturday, Sunday or a day on which banking institutions in New York, New York are authorized by Law to remain closed.

1.5. "CCC" means a Country Commercialization Committee as defined in Section 3.12 of this Agreement.

1.6. "Combination Product" is defined in Section 1.58 of this Agreement.

1.7. "Compound" means SEARLE's cyclooxygenase-2 inhibitor, celecoxib 4-[5-(4-methylphenyl)-3-trifluoromethyl-1H-pyrazol-1-yl]benzenesulfonamide, and any salts or polymorphs thereof.

1.8. "Co-Marketing Country" means a Country listed as a Co-Marketing Country on Exhibit 1.8, as amended from time to time.

1.9. "Co-Promotion" means the joint commercialization of the Product or the Second Generation Product (including, more generally, commercialization of cyclooxygenase-2 inhibitor technology ("Cox-2 Technology Promotion") without reference to a single product) pursuant to the Co-Promotion Plan(s) and Global Marketing Plans in effect from time to time.

1.10. "Co-Promotion Budget(s)" means the budget(s), as included in the Co-Promotion Plan(s) approved pursuant to Section 3.7, to co-promote the Product or Second Generation Product as defined in the U.S. Agreements and International Collaboration Agreements.

1.11. "Co-Promotion Country" means a Country listed as a Co-Promotion Country on Exhibit 1.11, as amended from time to time.

1.12. "Co-Promotion Plan(s)" means the plan(s) approved pursuant to Section 3.7 and developed in connection with the Co-Promotion of the Product or Second Generation Product as defined in the U.S. Agreements and International Collaboration Agreements.

1.13. "Co-Promotion Term" has the meaning ascribed thereto in the U.S. Agreements and the International Collaboration Agreements, respectively.

1.14. "Co-Promotion Territory" consists of the Co-Promotion Countries.

1.15. "Country" means a Co-Promotion Country, Co-Marketing Country, or PFIZER Exclusive Country.

1.16. "Cox-2 Technology Promotion" is defined in Section 1.9 of this Agreement.

1.17. "CSC" means the Collaboration Steering Committee as defined in Section 3.3.

1.18. "DC" means the Development Committee as defined in Section 3.8 of this Agreement.

1.19. "Detail" means a face-to-face contact (including a live video presentation) of either a SEARLE or PFIZER Sales Representative (or their respective designees), as the case may be, with a medical professional with prescribing authority, as measured by each party's internal recording of such

activity. With respect to certain group or institution Product presentations, Exhibit 1.19 sets forth how such presentations will be counted for determination of the number of Details. A Detail does not include a reminder presentation or a sample drop.

1.20. "Development Budget(s)" means the budget(s), as included in the Development Plan(s) adopted pursuant to Section 3.2(b), for the development of the Product or Second Generation Product.

1.21. "Development Costs" means all Out-of-Pocket Costs incurred by a party in the development of the Product or the Second Generation Product or any line extensions or formulations pursuant to the relevant Development Plan(s) and Development Budget(s). Such costs shall include, but not be limited to the following, provided that Development Costs shall exclude Out-of-Pocket Costs incurred prior to 1998 and Out-of-Pocket Costs incurred in connection with the commercial scale manufacture of the Product or the Second Generation Product:

- (1) the cost of materials used in the development of the Product or the Second Generation Product;
- (2) costs for outside professional services, including, but not limited to, toxicology studies or clinical studies performed by third parties;
- (3) direct charges for materials (including chemicals, animals and lab supplies);
- (4) costs incurred in connection with regulatory submissions; and
- (5) costs for process development of the Product or the Second Generation Product (other than process development for commercial scale manufacture).

Any Out-of-Pocket Costs that may be allocated either to Development Costs or Promotion Expenses shall be allocated to Promotion Expenses.

1.22. "Development Plan(s)" means the plan(s) adopted pursuant to Section 3.2(b) for the continued development of the Product and the Second Generation Product.

1.23. "EMC" means the Executive Management Committee as defined in Section 3.2 of this Agreement.

1.24. "EMEA" means the European Medicines Evaluation Agency.

1.25. "Europe" consists of the Countries in the European Union and the Country of Turkey.

1.26. "FDA" means the United States Food and Drug Administration and any successor agency thereto.

1.27. "GAAP" means U.S. generally accepted accounting principles, consistently applied.

1.28. "GCC" means the Global Commercialization Committee as defined in Section 3.6 of this Agreement.

1.29. "Global Marketing Budget(s)" means the budget(s), as included in the Global Marketing Plan(s) adopted pursuant to Section 3.2(b), for the commercialization of the Product or the Second Generation Product.

1.30. "Global Marketing Plan(s)" means the plan(s) for commercialization of the Product and the Second Generation Product adopted by the EMC on a yearly basis pursuant to Section 3.2(b), covering the following:

- (1) overall marketing objectives and strategy (including Product or Second Generation Product market positioning);
- (2) overall global level of marketing, sales and promotion efforts by each party;
- (3) global and major market and sales targets;
- (4) global and regional pricing analyses;
- (5) core global or cross-border advertising, public relations and other promotional programs, including medical education, professional symposia, publication and strategies to be used in the promotion of the Product or Second Generation Product; and
- (6) global strategic clinical plan that includes, Phase IIb-IV studies and pharmacoeconomic studies (excluding single country studies).

1.31. "Governmental Authority" means any court, agency, department or other instrumentality of any government or of any national, federal, state, provincial, regional, county, city or other political subdivision of any government in the United States, the Co-Promotion Territory or the License Territory or any supranational organization of which a Country is a member, including the European Union and the European Economic Area.

1.32. "IND" means an Investigational New Drug Application filed with the FDA.

1.33. "International Agreements" means the International Collaboration Agreements and the International License Agreements.

1.34. "International Collaboration Agreement" means the International Collaboration Agreement contemplated in Section 2.1 of this Agreement.

1.35. "International Collaboration Agreements" means collectively the International Collaboration Agreement and the International Second Generation Collaboration Agreement.

1.36. "International Second Generation Collaboration Agreement" means the International Collaboration Agreement (Second Generation) contemplated in Section 2.1 of this Agreement.

1.37. "International License Agreement" means the International License Agreement (Celecoxib) contemplated in Section 2.2 of this Agreement.

1.38. "International License Agreements" means collectively the International License Agreement and the International Second Generation License Agreement.

1.39. "International Second Generation License Agreement" means the International License Agreement (Second Generation) contemplated in Section 2.2 of this Agreement.

1.40. "Know-How" means all discoveries, inventions, designs, formulae, algorithms, assays, processes, software, apparatus, methods, copyrights, trade secrets, know-how, information and other technology, as well as improvements related thereto, which SEARLE or one of its Affiliates owns as of the Effective Date or otherwise has the right to use, whether patentable or otherwise, which is useful in the development, manufacture, importation, use and/or sale of the Compound, Second Generation Compound, the Product or the Second Generation Product.

1.41. "Law" or "Laws" means all laws, statutes, rules, regulations, orders, judgments and/or ordinances of any Governmental Authority.

1.42. "License Term" means the respective terms of the licenses granted under the International License Agreement and the International Second Generation License Agreement.

1.43. "License Territory" consists of all the Co-Marketing Countries and PFIZER Exclusive Countries.

1.44. "MAA" means Market Authorization Application under applicable Law in the Countries.

1.45. "Major European Country" means any of France, Germany, Italy, Spain and the United Kingdom.

1.46. "Month" means either a calendar month or a fiscal month in a calendar year.

1.47. "MSC" means the Manufacturing/Supply Committee as defined in Section 3.13 of this Agreement.

1.48. "NDA" means a New Drug Application filed with the FDA with respect to a Product or Second Generation Product.

1.49. "Net Sales" means the gross amount invoiced on sales or other dispositions of a Product or Second Generation Product to independent third parties, less the following items: (a) trade, cash and quantity and promotional discounts actually allowed and taken; (b) excise, sales, value added or other taxes imposed upon and paid with respect to such sales (excluding taxes based on income); (c) freight, insurance and other transportation charges incurred in shipping a Product or Second Generation Product to third parties and included in the amount invoiced to such third parties; (d) amounts repaid or credited by reason of rejections, defects, recalls or returns or retroactive price reductions; and (e) rebates or discounts pursuant to agreements or applicable Law. Any of the items set forth above which are charged to third parties shall not be included in Promotion Expenses.

If a Product or Second Generation Product is sold, used or otherwise commercially disposed of for value (including, without limitation, disposition in connection with the delivery of other products or services) in a transaction that is not an arm's length sale to an independent third party, then the gross amount invoiced in such transaction shall be deemed to be the gross amount that would have been paid had there been such a sale at the average sale price of such Product or Second Generation Product during the applicable reporting period.

1.50. "New Information" means any and all ideas, inventions, writings, discoveries, improvements, and all confidential knowledge, not generally known to the public, which may arise or be conceived or developed by either party or jointly during the term of this Agreement pursuant to the Development Plan(s) which relate to the Compound, Second Generation Compound, Product or Second Generation Product.

1.51. "OpCom" means the Operations Management Committee as defined in Section 3.4 of this Agreement.

1.52. "Out-of-Pocket Costs" means costs and expenses paid or accrued as owing to third parties, other than Affiliates or employees or third party contract Sales Representatives, by either party.

1.53. "Patent Rights" means all patents and patent applications (which for all purposes of this Agreement shall be deemed to include supplementary protection certificates, certificates of invention, applications for certificates of invention and utility models) in the Co-Promotion Territory and License Territory, covering or relating to the Compound, Second Generation Compound, Product or the Second Generation Product, including any substitutions, extensions, reissues, reexaminations, renewals, divisions or continuations or continuations-in-part, which SEARLE or one of its Affiliates owns as of the Effective

Date or has licensed from a third party, including but not limited to the patents and patent applications listed in Exhibit 1.53.

1.54. "Person" means and includes an individual, a company, a firm, a partnership, a joint venture, a corporation, a limited liability company, a trust, an estate, an unincorporated association or any other organization of any kind.

1.55. "Phase II" and "Phase III" means the phases of clinical development of Second Generation Product as defined in the Act, and the end of Phase II and Phase III mean the phases of clinical development of Second Generation Product as described on Exhibit 1.55.

1.56. "PFIZER Exclusive Country" means a Country listed as a PFIZER Exclusive Country on Exhibit 1.56, as amended from time to time.

1.57. "Price Approval" means, in Countries where Governmental Authorities approve or determine pricing for pharmaceutical products for reimbursement or otherwise, such approval or determination, which approval or determination shall be acceptable to the party applying therefor.

1.58. "Product" means, except as provided otherwise in the Agreements, any product containing the Compound as the sole active ingredient, or the Compound in combination with another active ingredient ("Combination Product"), for therapeutic use in humans, including all dosage forms, formulations and indications.

1.59. "Product Launch" means the first date of commercial sale of Product to unaffiliated third parties in such quantities as are customarily required for the general introduction of a pharmaceutical product in the United States, a Co-Promotion Country, a Co-Marketing Country or a PFIZER Exclusive

Country, as the context may require. SEARLE shall promptly notify PFIZER of the date of such sale, except that in PFIZER Exclusive Countries, PFIZER shall promptly notify SEARLE of the date of such sale.

1.60. "Promotional Material" means promotional, advertising, communication and educational materials relating to the Product or Second Generation Product.

1.61. "Promotion Expenses" shall include, but not be limited to, the following Out-of-Pocket Costs incurred by a party to the extent consistent with the relevant Global Marketing Plan and Co-Promotion Plan for the United States and the Co-Promotion Countries, adopted or approved pursuant to Sections 3.2(b) and 3.7(a), respectively, and related to the promotion of the Product, the Second Generation Product or the Cox-2 Technology Promotion in accordance with GAAP, except to the extent expressly provided below:

- (1) any consideration paid to third parties for licenses required to import, sell or use (but not manufacture) the Product or the Second Generation Product, other than with respect to patents which shall be subject to agreement among the parties (such agreement not to be unreasonably withheld);
- (2) pre-launch promotional expenses and post-regulatory approval medical and clinical trial costs (including, Phase IIb-IV marketing trials in the Global Marketing Plan), costs of pharmaco-economic studies, trial use studies, and third-party grants; costs of monitoring adverse drug reactions; and costs associated with securing and maintaining regulatory approvals;
- (3) costs of distributing and shipping the Product or the Second Generation Product to wholesalers, distributors and customers (including costs of processing or destroying returns); costs of collection; and bad debts;

- (4) costs, specifically related to the Product or the Second Generation Product, incurred for: (i) materials and programs related to the Product or the Second Generation Product used for training of sales force, regional sales management and marketing management; (ii) advertising (including agency fees); (iii) promoting (including detail aids, leave-behinds and all other materials); and (iv) marketing the Product or the Second Generation Product through any means (including advertisements, promotional literature, market research, symposia, medical meetings, speaker and activity programs, field and headquarters' grants directly relating to the Product or Second Generation Product, exhibits and direct mail);
- (5) costs associated with registering or maintaining the Trademark, and the Patent Rights for the Compound or the Second Generation Compound, the Product or the Second Generation Product;
- (6) costs associated with any communication mandated by a Governmental Authority, other than product recalls which shall be in accordance with the other Agreements; and
- (7) costs of samples when shipped to SEARLE or PFIZER distribution facilities pursuant to the applicable Co-Promotion Plan(s) or Global Marketing Plan(s) at the fully absorbed actual cost as applicable in the year such samples were manufactured.

All other Out-of-Pocket Costs that have not been specifically identified above or in Section 1.49 shall be accounted for as a Promotion Expense. The foregoing shall not include Out-of-Pocket Costs (i) incurred prior to January 1, 1998, (ii) incurred in connection with the manufacture of the Product or Second Generation Product, (iii) to the extent that such Out-of-Pocket Costs have been included in Development

Costs, and (iv) for each of the last two (2) Years during the Co-Promotion Term, in excess of one hundred twenty-five percent (125%) of Promotion Expenses for Year Ten, unless otherwise agreed by SEARLE and PFIZER. In addition, in the event that both parties are engaging, on a substantially equal basis, in activities in connection with the promotion of the Product or Second Generation Product and either party engages any third party to provide services in connection with such activities where such services are usually provided by the other party's internal resources, any payments to such third party for the services provided shall not be included in Promotion Expenses.

1.62. "RC" means the Regulatory Committee as defined in Section 3.10.

1.63. "Sales Representative" means an individual who engages in detailing and other promotional efforts with respect to the Product or Second Generation Product and who has been trained by either party, regardless of whether such individual is employed by either party, provided that Sales Representative shall not include any individual employed by a third party who also engages in the detailing and promotion of any products of such third party.

1.64. "SEARLE Exclusive Country" means any country listed as a SEARLE Exclusive Country on Exhibit 1.64 as amended from time to time.

1.65. "Second Generation Agreements" means the U.S. Second Generation Collaboration Agreement, the International Second Generation Collaboration Agreement, and the International Second Generation License Agreement.

1.66. "Second Generation Compound" means SEARLE's cyclooxygenase-2 inhibitor, 4-[5-methyl-3-phenylisoxazol-4-yl]benzenesulfonamide, and any salts, polymorphs, and active metabolites thereof.

1.67. "Second Generation Product" means, except as otherwise provided in the Agreements, any product containing the Second Generation Compound as the sole active ingredient, or the Second Generation Compound in combination with another active ingredient ("Combination Second Generation Product") for therapeutic use in humans, including all dosage forms, formulations and indications, other than parenteral, non-prescription and over-the-counter ("OTC") forms.

1.68. "Second Generation Product Launch" means the first date of commercial sale of Second Generation Product to unaffiliated third parties in such quantities as are customarily required for the general introduction of a pharmaceutical product in the United States, a Co-Promotion Country, a Co-Marketing Country, or a PFIZER Exclusive Country. SEARLE shall promptly notify PFIZER of the date of such sale, except that in a PFIZER Exclusive Country, PFIZER shall promptly notify SEARLE of the date of such sale.

1.69. "Territory" means the United States, the Co-Promotion Territory and the License Territory.

1.70. "Trademark" means the trademark(s) associated with the Product and the Second Generation Product.

1.71. "United States" means the United States of America, its territories, possessions and Puerto Rico.

1.72. "U.S. Agreements" means the U.S. Collaboration Agreement and the U.S. Second Generation Collaboration Agreement.

1.73. "U.S. Collaboration Agreement" means the U.S. Collaboration Agreement (Celecoxib) between MONSANTO, SEARLE, and PFIZER of even date herewith.

1.74. "U.S. Second Generation Collaboration Agreement" means the U.S. Collaboration Agreement (Second Generation) between MONSANTO, SEARLE, and PFIZER of even date herewith.

1.75. "Year" means each consecutive period of three hundred and sixty-five (365) days (or three hundred sixty-six (366) days in any leap year) commencing on the date of a Product Launch or a Second Generation Product Launch or any anniversary thereof during the term of this Agreement. "Year Two" means the three hundred and sixty-five (365) day period commencing on the first day following the expiration of Year One; references to Years Three through Year Twelve mean the successive three hundred and sixty-five (365) day periods thereafter. The term "year", without an initial upper case letter, means calendar year.

## ARTICLE 2

### CO-PROMOTION AND LICENSE RIGHTS

2.1. Co-Promotion. (a) SEARLE hereby agrees to grant to PFIZER exclusive rights, together with SEARLE, to promote and detail the Product and the Second Generation Product in the United States pursuant to the terms of the U.S. Agreements. SEARLE hereby agrees to grant to PFIZER rights to co-promote the Product and the Second Generation Product in the Co-Promotion Territory pursuant to the terms of an International Collaboration Agreement and an International Second Generation Collaboration Agreement to be negotiated and executed by the parties, the form and content of which shall be substantially the same as the form and content of the U.S. Agreements, with such modifications as are appropriate to reflect the terms set out in the Heads of Agreement in Exhibit 2.1.

(b) Promotion Expenses that benefit only the United States or a particular Country shall be allocated to the United States or that Country (as the case may be). All Promotion Expenses not so allocated shall be shared and paid by the parties as Promotion Expenses at the time and in the manner specified in the U.S. Agreements and the International Collaboration Agreements. To the extent that PFIZER makes a payment to SEARLE pursuant to Section 2.1, PFIZER shall make such payment to SEARLE and/or a single Affiliate, as directed by SEARLE, in a manner consistent with the Agreements.

2.2. Licenses. SEARLE hereby agrees to grant to PFIZER license rights to the Product and Second Generation Product in the License Territory pursuant to the terms of an International License Agreement and an International Second Generation License Agreement to be negotiated and executed by the parties, which agreements shall reflect the terms set out in the Heads of Agreement in Exhibit 2.2. With respect to Co-Marketing Countries, SEARLE shall grant to PFIZER license rights necessary to market, promote, detail, distribute and sell the Product and Second Generation Product together with SEARLE during the License Term in each such Country. With respect to PFIZER Exclusive Countries, SEARLE shall grant to PFIZER exclusive license rights necessary to market, promote, detail, distribute and sell the Product and Second Generation Product during the License Term in each such Country. In the License Territory, PFIZER shall be responsible for its own marketing, promotion, detailing, distribution and sales with respect to the Product and Second Generation Product, provided that the foregoing activities shall, to the extent permitted under applicable Laws, be conducted in a manner consistent with the guidelines and directives of the OpCom as reflected in the Global Marketing Plan, but nothing contained herein is intended to give one party any control or influence over the other party's export policies, customer selection, prices charged, discounts offered, sales and promotion expenses, or terms of sale utilized.

Except as otherwise provided in Section 11.19, PFIZER shall have access to any and all scientific and regulatory data, materials and filings owned by SEARLE with respect to the Product and Second Generation Product as necessary for the purpose of the foregoing activities.

2.3. Conversion of Countries. (a) Notwithstanding anything to the contrary contained in the Agreements, at any time from the Effective Date through and including the period ending three (3) years from the date of Product Launch (or three (3) years from the date of Second Generation Product Launch for Second Generation Product only) in a particular Country, SEARLE may elect, upon not less than one hundred eighty (180) days written notice to PFIZER, to convert any PFIZER Exclusive Country to a Co-Promotion Country or, if the applicable Law in such Country does not permit the conversion into a Co-Promotion Country, to a Co-Marketing Country. During the one hundred eighty (180) days following the receipt of SEARLE's notice of election, the parties shall undertake the development of a joint marketing plan. Any such conversion shall be effective as of the close of business on the date which is one hundred eighty (180) days from the date of such notice (the "Conversion Date").

(b) If a PFIZER Exclusive Country is converted into a Co-Promotion Country within three (3) years of Product Launch, then, no later than two (2) months prior to the Conversion Date, PFIZER shall deliver to SEARLE a statement (an "Interim Statement") setting forth in detail itemized Development Costs and Promotion Expenses for all Product and Second Generation Product and, if the Conversion Date is on or prior to the date of Product Launch, all internal costs incurred by PFIZER in relation to the Country in question directly related to the Product and Second Generation Product ("Internal Costs"), or, if the Conversion Date is after the date of Product Launch, PFIZER's Net Sales of the Product and Second

Generation Product in the Country (if any) for the nine (9) month period ending on the date that is three (3) months prior to the Conversion Date. SEARLE shall pay to PFIZER, within thirty (30) days following receipt of the Interim Statement, an amount equal to fifty percent (50%) of Internal Costs (but only if the Conversion Date is prior to the date of Product Launch), fifty percent (50%) of Development Costs and Promotion Expenses, and one hundred (100%) of the Net Sales (if applicable), all as shown on the Interim Statement. No later than thirty (30) days following the Conversion Date, PFIZER shall deliver to SEARLE a statement (the "Conversion Date Statement") setting forth, in detail, Internal Costs (but only if the Conversion Date is prior to the date of Product Launch), Development Costs and Promotion Expenses for all Product and Second Generation Product during the three (3) month period ending on and including the Conversion Date and PFIZER's Net Sales of the Product and the Second Generation Product in the Country (if any) for the three (3) month period ending on the Conversion Date. SEARLE shall pay to PFIZER, within thirty (30) days following receipt of the Conversion Date Statement, an amount equal to fifty percent (50%) of Internal Costs (but only if the Conversion Date is prior to the date of Product Launch), fifty percent (50%) of Development Costs and Promotion Expenses and one hundred (100%) of such Net Sales, all as shown on the Conversion Date Statement.

(c) If a PFIZER Exclusive Country is converted into a Co-Promotion Country less than three (3) years after the date of Second Generation Product Launch in such Country but more than three (3) years after the date of Product Launch, the conversion shall only apply to the Second Generation Product. In such event, the payment amounts and procedures set forth in Section 2.3(b) shall apply but only with respect to the Second Generation Product.

(d) The International Collaboration Agreement or the International Second Generation Collaboration Agreement, as the case may be, will become applicable with respect to any Country so

converted to a Co-Promotion Country pursuant to Section 2.3(b), (c) or (f) as of the Conversion Date, and any and all ongoing Development Costs and Promotion Expenses pertaining to such Co-Promotion Country and incurred by either party following the Conversion Date shall be shared equally by the parties; provided, however, that for a reasonable transition period PFIZER shall be entitled to continue to purchase Product and Second Generation Product and book sales thereof but shall then pay SEARLE sixty percent (60%) of such Net Sales or, if during any period from the Effective Date through and including Year Three that Merck & Co., Inc. and its affiliates are not marketing or selling a cyclooxygenase-2 inhibitor product in such Country, sixty-five percent (65%) of such Net Sales, so as to achieve the same economic result as that set out in the International Collaboration Agreements.

(e) If a PFIZER Exclusive Country is converted into a Co-Marketing Country, then, no later than two (2) months prior to the Conversion Date, PFIZER shall deliver to SEARLE an Interim Statement setting forth in detail itemized Development Costs and Promotion Expenses for all Product and Second Generation Product, all Internal Costs incurred by PFIZER in relation to the Country in question directly related to complying with the registration requirements of the Country for the Product and Second Generation Product ("Internal Registration Costs"), and PFIZER's Net Sales of the Product and Second Generation Product in the Country (if any) for the nine (9) month period ending on the date that it is three (3) months prior to the Conversion Date. SEARLE shall pay to PFIZER, within thirty (30) days following receipt of the Interim Statement, an amount equal to fifty percent (50%) of such Internal Registration Costs (but only if SEARLE wishes to use PFIZER's files), fifty percent (50%) of such Development Costs and Promotion Expenses, and twenty-five (25%) of the Net Sales, all as shown on the Interim Statement. No later than thirty (30) days following the Conversion Date, PFIZER shall deliver to SEARLE a Conversion Date Statement setting forth, in detail, Internal Registration Costs, Development Costs and Promotion Expenses for the Product and Second Generation Product and all Internal Registration Costs incurred by

PFIZER in relation to the Country in question during the three (3) month period ending on and including the Conversion Date and PFIZER's Net Sales of the Product and the Second Generation Product in the Country (if any) for the three (3) month period ending on the Conversion Date. SEARLE shall pay to PFIZER, within thirty (30) days following receipt of the Conversion Date Statement, an amount equal to fifty percent (50%) of such Internal Registration Costs (but only if SEARLE wishes to use PFIZER's files), fifty percent (50%) of such Development Costs and Promotion Expenses and twenty-five percent (25%) of such Net Sales, all as shown on the Conversion Date Statement. The International License Agreement or the International Second Generation License Agreement, as the case may be, will remain applicable with respect to such Country, any and all ongoing Development Costs shall be shared equally by the parties, and Promotion Expenses shall be borne independently by the parties. In the event of any conversion of a PFIZER Exclusive Country into a Co-Marketing Country, PFIZER shall retain all rights in and to the Trademarks in use, and the goodwill related thereto, in such Country, during the term of the Agreement.

(f) At any time after the end of Year Three, in the event that (i) the sales in United States Dollars of the Product together with the Second Generation Product, if applicable, shall not have achieved a number two (2) or greater market share position in the prescription NSAID and Cox-2 market (excluding generics) in a particular PFIZER Exclusive Country (for which IMS market share data are available) for any two (2) complete consecutive Years following Year Three or (ii) in countries where IMS data is not available, SEARLE can demonstrate that PFIZER has materially failed in any such two (2) consecutive Years to use commercially reasonable efforts to meet its obligations as set forth in the relevant operating plans submitted to the GCC in accordance with the International License Agreement, then as of such second Year end, SEARLE shall have the option, upon not less than one hundred eighty (180) days written notice to PFIZER given within sixty (60) days after the end of such second Year, to convert such PFIZER Exclusive Country to a Co-Promotion Country or, if applicable Law in such Country does not permit the conversion into a Co-Promotion Country, to a Co-Marketing Country. During the one hundred

eighty (180) days following the receipt of SEARLE's notice of election, the parties shall undertake the development of a joint marketing plan. Any such conversion shall be effective as of the close of business on the date which is one hundred eighty (180) days from the date of such notice (the "Conversion Date"). If such PFIZER Exclusive Country is converted into a Co-Promotion or Co-Marketing Country, as the case may be, within thirty (30) days following receipt of such notice, PFIZER shall deliver to SEARLE a statement setting forth, in detail, its Net Sales of the Product and Second Generation Product in the Country (if any) for the twelve (12) month period ending on the Conversion Date. SEARLE shall pay to PFIZER, within thirty (30) days following the receipt of PFIZER's statement of Net Sales, an amount equal to the amount of Net Sales shown on such statement. The International Collaboration Agreement or the International Second Generation Collaboration Agreement, as the case may be, will become, or the International License Agreement or the International Second Generation License Agreement, as the case may be, will remain applicable with respect to such Country, and any and all ongoing Development Costs and Promotion Expenses shall be borne or shared according to the applicable International Agreement provided, however, that if such PFIZER Exclusive Country is converted to a Co-Promotion Country, PFIZER shall be entitled for a period of six (6) months from the Conversion Date to continue to purchase Product and Second Generation Product and book sales thereof but shall then pay SEARLE sixty percent (60%) of such Net Sales or, if during any period from the Effective Date through and including Year Three that Merck & Co., Inc. and its affiliates are not marketing or selling a cyclooxygenase-2 inhibitor product in such Country, sixty-five percent (65%) of such Net Sales, so as to achieve the same economic result as that set out in the International Collaboration Agreements.

(g) In the event PFIZER shall fail to file for approval for the marketing and sale of the Product or Second Generation Product in a PFIZER Exclusive Country within four (4) months of the date of Product Launch or Second Generation Product Launch, respectively, in the United States, or if PFIZER

shall discontinue, without reasonable justification, the marketing and sale of the Product or Second Generation Product in a PFIZER Exclusive Country, SEARLE shall have the option, within sixty (60) days of the expiration of such four (4) months period or discontinuation, to eliminate such Country as a PFIZER Exclusive Country for both Product and Second Generation Product and such Country shall be subject to the terms and conditions of Section 2.4 below; provided that with respect to such Country, for the remainder of the term hereof, PFIZER shall have no obligation to pay any cost or expense relating to Product or Second Generation Product and shall not be entitled to receive any portion of the Net Sales thereof in such Country.

2.4. Other Countries. Marketing of the Product and Second Generation Product in any country which is not the United States, a Co-Promotion Country, a Co-Marketing Country, a PFIZER Exclusive Country, or a SEARLE Exclusive Country shall be determined by the GCC and this Section 2.4. PFIZER shall pay twenty-five (25%) and SEARLE shall pay seventy-five percent (75%) of any cost or expense relating to Product or Second Generation Product and the parties shall be entitled to receive twenty-five percent (25%) and seventy-five percent (75%), respectively, of the Net Sales in all Countries other than the United States, Co-Promotion Countries, Co-Marketing Countries, PFIZER Exclusive Countries, SEARLE Exclusive Countries, Japan, or a Country ceasing to be a PFIZER Exclusive Country pursuant to Section 2.3(g) above. In a SEARLE Exclusive Country, SEARLE shall have exclusive control over marketing, promotion, detailing, distribution and sale of the Product and the Second Generation Product, and shall bear all costs and have all rights to profits with respect thereto. Japan is excluded from the Agreements and SEARLE shall retain all rights with respect to the Product and Second Generation Product in Japan and shall be free to license, transfer or otherwise dispose of such rights to any third party.

2.5. Termination of Rights. In addition to PFIZER's termination rights in any other Agreement, PFIZER's rights and obligations with respect to the Second Generation Product pursuant to the Second Generation Agreements ("Rights") may be terminated under the following circumstances:

(a) Promptly following the completion of Phase II, SEARLE shall notify PFIZER of said completion and shall provide PFIZER with all material clinical data and the opportunity to review other clinical data, non-clinical data and regulatory communications resulting from Phase II, together with all final study reports relating thereto and a Phase III development plan which includes (i) a summary of overall cost of development through NDA filing, (ii) a list of all additional planned clinical and pre-clinical studies up to the time of NDA filing, with anticipated costs and (iii) a global and regional commercial assessment and labeling strategy of primary indications. PFIZER shall have sixty (60) days from the receipt of the foregoing to notify SEARLE that it elects to retain the Rights or to forfeit the Rights. In the event that PFIZER elects to forfeit the Rights, all Second Generation Agreements shall terminate immediately. In the event that PFIZER elects to retain the Rights, PFIZER shall pay SEARLE fifty percent (50%) of all FTE Costs incurred by SEARLE from January 1, 1998 through completion of Phase II. For purposes of this Section, "FTE Costs" means the fully-loaded costs, including ordinary lab supplies and any reasonable travel costs, but excluding general corporate overhead, of a full-time equivalent scientific/technical person dedicated to the development of a product as carried out by an employee having skills in a biological, chemical or physical science or in the areas of clinical research, statistics, project management or regulatory affairs. The parties will use a rate of Two Hundred Thousand Dollars (\$200,000) per calendar year (beginning with 1998) for FTE Costs for each such person. Such rate shall be adjusted annually for inflation based on changes in the Bureau of Labor Statistics Consumer Price Index for Urban Wage Earners - U.S. city Average, from the prior January 1st. PFIZER shall also continue to pay to SEARLE fifty percent (50%) of all ongoing Development Costs with respect to the Second Generation Product pursuant to the provisions of the Agreements. If PFIZER fails to notify SEARLE within such sixty (60) day period of its election, PFIZER

shall be deemed to have irrevocably elected to forfeit the Rights, and all Second Generation Agreements shall terminate immediately.

(b) In the event PFIZER elects to retain the Rights pursuant to Section 2.5(a), promptly following the completion of Phase III, SEARLE shall notify PFIZER of said completion and shall provide PFIZER with all material clinical data and non-clinical data and regulatory communications resulting from Phase III (it being understood that PFIZER shall have throughout Phase III access to all data as it becomes available). PFIZER shall have thirty (30) days from the end of Phase III (as defined in Exhibit 1.55) to notify SEARLE that it elects to retain the Rights or to forfeit the Rights, provided, however, that if SEARLE shall not have delivered its Statement pursuant to Section 4.4(d) to PFIZER, but PFIZER has provided its Statement to SEARLE, PFIZER shall have until the seventh (7th) Business Day following the date SEARLE's Statement is delivered to make such election. In the event that PFIZER elects to forfeit the Rights, the Second Generation Agreements shall terminate immediately. In the event that PFIZER elects to retain the Rights, PFIZER shall continue to pay to SEARLE fifty percent (50%) of all ongoing Development Costs with respect to the Second Generation Product pursuant to Section 4.3. If PFIZER fails to notify SEARLE within such thirty (30) day period of its election, PFIZER shall be deemed to irrevocably have elected to forfeit the Rights and all Second Generation Agreements shall terminate immediately.

(c) If PFIZER forfeits the Rights and SEARLE subsequently enters into a co-promotion, license, sale of rights, or joint venture agreement for the Second Generation Product with an unrelated third party for (i) the United States, SEARLE shall refund to PFIZER seventy percent (70%) of all amounts paid by PFIZER to SEARLE pursuant to Section 2.5(a) and (b) and (ii) any two Major European

Countries, SEARLE shall refund to PFIZER thirty percent (30%) of all amounts paid by PFIZER to SEARLE pursuant to Section 2.5(a) and (b).

2.6. Exclusivity. During the period beginning on the Effective Date and ending on PFIZER's forfeiture of the Rights pursuant to Section 2.5(a) or Section 2.5(b), as applicable, of this Agreement, SEARLE shall not, nor shall it permit any of its Affiliates to, nor shall it authorize or permit any officer, director or employee or any investment banker, attorney or other advisor or representative of SEARLE or any of its Affiliates to, directly or indirectly, (i) solicit, initiate or encourage the submission of any proposal regarding the purchase, transfer, license, "co-promotion", "co-marketing" or creation of any partnership or joint venture involving the Second Generation Product or the Second Generation Compound (any such transactions, the "Transactions"), or (ii) participate in any discussions or negotiations regarding, or furnish to any person or group any information with respect to, or take any other action to facilitate any inquiries or the making of any proposal that constitutes or may reasonably be expected to lead to any Transaction proposal, or (iii) engage in or consummate any Transactions, provided, however, that nothing contained herein shall prevent SEARLE from discussing such matter with Yamanouchi Pharmaceutical Co., Ltd. or SEARLE's potential marketing partners in Brazil and France with respect to such Countries.

2.7. Product Claim and Clinical Trials. Neither party shall make any medical claim for the Product or the Second Generation Product beyond the scope of the relevant regulatory approval(s) then in effect for the Product or the Second Generation Product; provided that both parties may distribute any information concerning the Product or the Second Generation Product or its use, including but not limited to scientific articles, reference publications, and healthcare economic information, in accordance with applicable Laws and subject to the oversight of the relevant CCC. In addition, neither PFIZER nor SEARLE shall conduct any clinical trials with respect to the Product or the Second Generation Product, except as approved by the DC and the GCC under Sections 3.7 and 3.9 of this Agreement, provided that SEARLE

shall be permitted to conduct any clinical trials independently with respect to any NCE Combination Product (as defined in the U.S. Collaboration Agreement).

## ARTICLE 3

### MANAGEMENT

3.1. Committees/Management. (a) The parties intend that SEARLE, acting through the committee structure described below, shall have the final decision making authority regarding development, regulatory, manufacturing and marketing matters relating to the Product or Second Generation Product, except only if such decision violates or breaches a specific provision of any of the Agreements. The parties acknowledge and agree that none of the committees formed or to be formed under any of the Agreements shall have the power to amend any of the terms or conditions of the Agreements.

(b) The parties agree to establish for the purposes specified under each Committee an Executive Management Committee, a Collaboration Steering Committee, an Operations Management Committee, a Global Commercialization Committee, a Manufacturing/Supply Committee, a Development Committee, a Regulatory Committee, and, for the United States and each Co-Promotion Country, a Country Commercialization Committee. All such Committees (including any sub-committees), except the Executive Management Committee and the Manufacturing/Supply Committee, shall have equal representation from the parties.

3.2. Executive Management Committee. The Executive Management Committee ("EMC") shall have five (5) members.

(a) Promptly after the Effective Date, SEARLE shall appoint three (3) representatives and PFIZER shall appoint two (2) representatives to the EMC. SEARLE shall appoint its Chief Executive

Officer, its Chief Operating Officer and its Chief Scientific Officer as its representatives and PFIZER shall appoint the President of Pfizer Pharmaceutical Group and the Executive Vice President of PFIZER responsible for worldwide research and development as its representatives. SEARLE shall also designate the chairperson of the EMC, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time if a new person is appointed to any of the foregoing positions by giving written notice to the other party.

(b) The responsibilities of the EMC shall be as follows:

- (1) review annually and adopt the Global Marketing Plan(s), Global Marketing Budget(s), Development Plan(s) and Development Budget(s), and regulatory plan(s) and regulatory budget(s) and review matters referred to it by the Committees, and
- (2) resolve any matters not resolved by the CSC, or by line management for CCC-related issues.

(c) The EMC shall meet whenever a party shall request or whenever a matter is referred to it by the CSC, or line management. The EMC shall make decisions by majority vote, each representative having a single vote but with voting by proxy allowed. The EMC shall have the final decision making authority with respect to all matters within the jurisdiction of any of the Committees established pursuant to this Article 3 or pursuant to one of the other Agreements which are referred to the EMC for determination or remain unresolved in the CSC, OpCom or other Committee. The EMC shall exercise this authority in good faith, all decisions shall have a reasonable basis, and any such decision shall be binding on the parties.

3.3 Collaboration Steering Committee. (a) The Collaboration Steering Committee ("CSC") shall have eight (8) members. Promptly after the Effective Date, SEARLE will appoint four (4)

representatives to the CSC and PFIZER will appoint four (4) representatives. SEARLE will designate the chairperson of the CSC, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time by giving written notice to the other party.

(b) The CSC shall have general oversight over, resolve issues from and review activities of the OpCom.

3.4. Operations Management Committee. The Operations Management Committee ("OpCom") shall have eight (8) members. Promptly after the Effective Date, SEARLE will appoint four (4) representatives to the OpCom and PFIZER will appoint four (4) representatives. The representatives of each party shall include members of other Committees and senior management from SEARLE and PFIZER. SEARLE will designate the chairperson of the OpCom, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time by giving written notice to the other party but the replacement representative must also be a member of the appropriate Committee or senior management from SEARLE or PFIZER.

3.5. OpCom Responsibilities. The responsibility of the OpCom shall be to review and recommend for adoption the Global Marketing Plans, Global Development Budgets, Development Plans, Development Budgets, regulatory plans and regulatory budgets in a consistent and coordinated manner consistent with the terms of the Agreements. In addition, the OpCom shall:

- (1) recommend the Global Marketing Plan(s) and Global Marketing Budget(s) for CSC review and adoption by the EMC;
- (2) recommend the Development Plan(s) and Development Budget(s) for CSC review and adoption by the EMC;

- (3) recommend regulatory plan(s) and budget(s) for CSC review and adoption by the EMC;
- (4) review and approve any material change in a Co-Promotion Plan or Development Plan or any deviation of ten percent (10%) or more in a Co-Promotion Budget or Development Budget;
- (5) resolve disputes referred by or remaining unresolved in the GCC, DC or RC;
- (6) recommend whether to abandon for any reason development of the Compound or the Second Generation Compound for approval by the EMC; and
- (7) recommend filing of the NDA(s) and all supplements or amendments thereto and all equivalent filings outside the United States.

3.6. Global Commercialization Committee. The Global Commercialization Committee ("GCC") shall have ten (10) members. Promptly after the Effective Date, SEARLE will appoint five (5) representatives to the GCC and PFIZER will appoint five (5) representatives. SEARLE will designate the chairperson of the GCC, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time by giving written notice to the other party.

3.7. GCC Responsibilities. (a) Subject to the terms of the Agreements, the GCC will prepare a Global Marketing Plan and Global Marketing Budget. The Global Marketing Plan(s) will not address local, Country level advertising, which will be the responsibility of the CCC, except for any matter referred by or unresolved in a CCC pursuant to Section 3.15(b). The Global Marketing Plan(s) shall be updated as deemed appropriate by the GCC, but in no event less frequently than each year. In addition, the GCC will:

- (1) review and approve Co-Promotion Plans and Co-Promotion Budgets for consistency with the Global Marketing Plan and Budget;
- (2) monitor compliance with Co-Promotion Plans and Co-Promotion Budgets;
- (3) coordinate a global strategic plan that optimizes the development of the Product and the Second Generation Product to optimize their commercial value;
- (4) on a global basis:
  - (i) develop core advertising materials and strategies and promotional materials;
  - (ii) design packaging; and
  - (iii) plan and conduct educational and professional symposia.

3.8 Development Committee. The Development Committee ("DC") shall have ten (10) members. Promptly after the Effective Date, SEARLE will appoint five (5) representatives to the DC and PFIZER will appoint five (5) representatives. SEARLE will designate the chairperson of the DC, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time by giving written notice to the other party.

3.9 DC Responsibilities. In general, the DC will oversee all development activities of the parties with respect to the Product and the Second Generation Product. The DC shall prepare a Development Plan for the continued development of the Product and the Second Generation Product for the United States and a particular Country or group of Countries and a related Development Budget, based upon the current plan and budget attached hereto as Exhibit 3.9 (which Exhibit shall be reviewed by the

appropriate committee pursuant to this Article 3, except as to committed spending). Each Development Plan shall recommend time lines and priorities for the various development activities and recommend which party, or whether a third party, is to be responsible for each activity. Each Development Plan shall be updated as deemed appropriate by the DC, but in no event less frequently than annually. Each Development Plan and changes therein shall be submitted to the OpCom for review and recommendation. Based on recommendations in each Development Plan, SEARLE may elect to have PFIZER, with its consent, undertake certain development activities. In addition, the DC will:

- (1) facilitate the exchange of all development information and dates;
- (2) review activities against the Development Plan(s) and related Development Budget(s);
- (3) recommend allocation of development activities among PFIZER, SEARLE and third parties; and
- (4) review specifications for the Product and the Second Generation Product.

3.10 Regulatory Committee. The Regulatory Committee ("RC") shall have four (4) members. Promptly after the Effective Date, SEARLE will appoint two (2) representatives to the RC and PFIZER will appoint two (2) representatives. SEARLE will designate the chairperson of the RC, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time by giving written notice to the other party.

3.11 RC Responsibilities. In general, the RC will oversee, monitor and coordinate all regulatory filings with and submissions to, including filings and submissions of supplements and amendments thereto, the FDA in the United States and Governmental Authorities elsewhere, including submissions of NDA's and

equivalent submissions outside the United States, with respect to the Product and the Second Generation Product. From time to time following the Effective Date, the RC shall initiate the preparation of reports on the status of all regulatory filings with and submissions to Governmental Authorities in the United States and the Countries in connection with the commercialization of the Product and the Second Generation Product including time lines for such filings and submissions. The RC shall submit such reports to the OpCom for its review and recommendation. In addition, the RC shall:

- (1) facilitate the exchange of all regulatory information and dates;
- (2) review activities against the regulatory plans and related regulatory budgets;
- (3) recommend allocation of regulatory activities among PFIZER, SEARLE and third parties; and
- (4) review specifications for the Product and the Second Generation Product.

3.12 Country Commercialization Committees. Prior to the date of Product Launch or Second Generation Product Launch in any Country, and as and when directed by the GCC, SEARLE will appoint one (1) or more representatives to a Country Commercialization Committee ("CCC") for each Country or group of Countries and PFIZER will appoint one (1) or more representatives, as the parties shall agree; provided that each party shall have an equal number of representatives on each CCC. SEARLE will designate the chairperson of each CCC, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time by giving written notice to the other party. Subject to the terms of the Agreements, the responsibilities of the CCC shall be as provided in the U.S. Agreements and the International Collaboration Agreements.

3.13 Manufacturing/Supply Committee. The Manufacturing/Supply Committee ("MSC") shall have seven (7) members. Promptly after the Effective Date, SEARLE will appoint four (4) representatives to the MSC and PFIZER will appoint three (3) representatives. SEARLE will designate the chairperson of the MSC, which designation may be changed by SEARLE at any time. A party may change any of its representatives at any time by giving written notice to the other party.

3.14 MSC Responsibilities. Subject to the terms of the Agreements, the MSC shall be an advisory committee with regard to the following matters (but as to which SEARLE shall have sole decision making authority):

- (a) develop a worldwide sourcing plan,
- (b) review production plans and set inventory guidelines for the Compound, the Second Generation Compound, the Product and the Second Generation Compound, and
- (c) evaluate available capacity and determine if additional third party supply is required.

The MSC shall report all results of its findings to the GCC and SEARLE.

3.15 Meetings of CSC, OpCom, GCC, DC and RC and Resolution of Matters.

(a) The chairperson of the CSC, the OpCom, the GCC, the DC and the RC, shall call meetings when deemed by the chairperson to be appropriate or when requested by PFIZER, currently anticipated to be quarterly. If possible, the meetings shall be held in person, or where appropriate, by video or telephone conference. The parties shall determine the form of the meeting. Decisions shall be made unanimously, each party having one (1) vote regardless of the number of representatives present or voting. Voting by proxy is permissible. Additional participants may be invited by any member to attend meetings

where appropriate (e.g., representatives of regulatory affairs or outside consultants). Such additional participants shall not be deemed, or have any rights or responsibilities of, a member of such committee.

(b) The parties shall cause their respective representatives on the Committees to use their best efforts to resolve all matters presented to them as expeditiously as possible. If any matter that is assigned to the responsibility of the CSC, OpCom, GCC, DC, or RC pursuant to this Article 3 cannot be resolved within the Committee, the parties represented on such Committees shall, in the most expeditious manner, resolve that matter or matters as follows: In the case of the CSC, the matter shall be referred to the EMC for resolution. In the case of the GCC or RC, the matter shall be referred to the OpCom for resolution, failing which it will be referred to the CSC and, if still unresolved, to the EMC. In the case of the DC, during the first three years from the Effective Date, if any matter cannot be resolved in the DC, the heads of research and development of SEARLE and PFIZER, respectively, shall meet with the Committee (in any manner provided in paragraph (a)) to resolve the matter, failing which SEARLE's head of research and development shall have the right to decide the matter. After the first three (3) years from the Effective Date, any matter that cannot be resolved in the DC shall be referred to the OpCom for resolution, failing which it shall be referred to the CSC and, if still unresolved, to the EMC for resolution. Any matter that cannot be resolved within a CCC in an expeditious manner shall be submitted to the GCC for mediation, and if still unresolved, referred to line management of SEARLE and PFIZER, failing which it shall be referred to the EMC for resolution. In the event any matter referred to the EMC cannot be resolved by the members of the EMC without submitting such matter to a final vote of the EMC, and PFIZER or MONSANTO, at its sole discretion, deems such matter to be material to the Co-Promotion and the relationship of the parties, an EMC member representing such party may elect to first refer the matter to the Chief Executive Officers of MONSANTO and PFIZER for consideration and resolution prior to submitting such matter to a final vote of the EMC.

3.16 Limitation on Clinical Studies. During the first eight (8) Years from Product Launch in the United States, in the event that SEARLE shall wish to conduct a clinical study, or a series of related studies involving Twenty Five Million Dollars (\$25,000,000) or more in Development Costs, the Development Plan with respect to such clinical study or studies shall include an economic rationale for the proposed study or studies, taking into account the nature of the study or studies, its total Development Costs, the time to market, a reasonable economic return to PFIZER, and the overall value of the indication, formulation, or labeling change that may result from such study or studies; provided, however, that subject to taking the foregoing factors into account the final decision whether to proceed with the clinical study shall rest with the EMC.

#### ARTICLE 4

##### DEVELOPMENT COSTS AND MILESTONES

4.1. Development Costs. (a) Any and all Development Costs incurred by either party pertaining directly or indirectly to the United States, the Co-Promotion Territory, and/or (to the extent permitted by applicable Law) the Co-Marketing Countries shall be shared equally by the parties as provided in Sections 4.2 and 4.3 below. Any and all Development Costs incurred in connection with a PFIZER Exclusive Country shall be borne by PFIZER, and any and all Development Costs incurred in connection with a SEARLE Exclusive Country shall be borne by SEARLE.

(b) Development Costs that benefit only the United States or a particular Country shall be allocated to the United States or that Country (as the case may be). All Development Costs shall be shared and paid by the parties at the time and in the manner specified in Sections 4.2 and 4.3. To the extent that PFIZER makes a payment to SEARLE pursuant to Article 4, PFIZER shall make such payment to SEARLE and/or a single Affiliate, as directed by SEARLE, in a manner consistent with the Agreements.

4.2. Sunk Development Costs. Within thirty (30) days following the Effective Date, SEARLE shall deliver to PFIZER a statement setting forth, in detail, all Development Costs incurred from January 1, 1998 through the Effective Date hereof. In further consideration of the rights granted to PFIZER with respect to the United States and the Co-Promotion Territory and/or Co-Marketing Countries, respectively, PFIZER shall pay to SEARLE within thirty (30) days following receipt of SEARLE's statement an amount equal to fifty percent (50%) of such Development Costs incurred by SEARLE. Exhibit 4.2 lists the projected Development Costs for this year, together with an estimate of Development Costs incurred by SEARLE this year from January 1, 1998 through the Effective Date hereof.

4.3. On-Going Development Costs. Within thirty (30) days after the end of each calendar quarter following the Effective Date, each party shall provide to the other party a written report summarizing in reasonable detail the development activities undertaken by such party pursuant to the relevant Development Plan during the preceding calendar quarter pertaining directly or indirectly to the United States and any Co-Promotion Country, together with a detailed statement of the related Development Costs incurred during such calendar quarter. Within thirty (30) days after the exchange of the progress reports, the parties shall determine if each party has borne an equal share of such Development Costs (in the aggregate) incurred during the applicable calendar quarter. Within thirty (30) days following such determination, an adjustment payment shall be made by one party to the other to the extent necessary to provide for an equal sharing of the such Development Costs (in the aggregate) for such calendar quarter.

4.4. Milestones. Certain milestone payments for the rights to co-promote the Product are provided for in the U.S. Collaboration Agreement and in Exhibit 2.1 relating to the International Agreements. Additional milestone payments with respect to the Second Generation Product are provided for in this Section 4.4.

(a) Upon PFIZER's election to retain the Rights pursuant to Section 2.5(b), the parties shall proceed immediately to determine the Present Value ("PV") of Second Generation Product Incremental Sales ("SGPIS") in accordance with the methodology and example set forth in Exhibit 4.4. Once determined, the following formula shall be applied:

$$\frac{\$450 \text{ million} \times \text{PV of SGPIS}}{\text{PV Current Product Sales Forecast}}$$

The Current Product Sales Forecast is also set forth in Exhibit 4.4.

The greater of (i) the amount determined under the foregoing formula, less all amounts paid by PFIZER to SEARLE pursuant to Sections 4.2 and 4.3 with respect to the Second Generation Product, and (ii) fifty (50) million dollars shall constitute the Second Generation Milestone Payment, which shall be apportioned among the Milestones in accordance with paragraph (c) below.

(b) The Annual Net Sales Goal for each of Year One, Year Two, and Year Three after the date of Second Generation Product Launch for the United States and Europe shall also be determined by the parties in accordance with Exhibit 4.4.

(c) In consideration of the right to Co-Promote the Second Generation Product in the United States and in the Co-Promotion Territory and in addition to the other payments provided for in the Agreements, PFIZER shall pay to SEARLE the percentage of the Second Generation Milestone Payment set forth opposite each event set forth below within thirty (30) days following the occurrence of such event:

Event	<u>Percentage</u>	
	<u>U.S.</u>	<u>Europe</u>
Final determination of the Second Generation Milestone Payment (in accordance with paragraph (a))	18.9%	3.4%
FDA acceptance for filing of a New Drug Application for the Second Generation Product	17.8%	
First approval of a New Drug Application for the Second Generation Product by the FDA		2.2%
Filing with validation of an MAA for the Second Generation Product with the EMEA or a Major European Country		13.3%

In addition, SEARLE shall use its best efforts to notify PFIZER within thirty (30) days that it has attained any of the Net Sales Goals set out below, and PFIZER shall pay to SEARLE within thirty (30) days of such SEARLE notification the percentage of the Second Generation Milestone Payment set forth under "Payment" below:

Year One		Year Two			Year Three			
	Year One Net Sales Goal		Year Two Net Sales Goal	Cumulative Net Sales Goal		Year Three Net Sales Goal	Cumulative Net Sales Goal	Payment
United States	\$ 7.775%	Payment	\$	\$	Payment	\$	\$	15.55%
Europe	\$ 3.325%		\$	\$	3.325%	\$	\$	6.65%

(1) With respect to Europe, Net Sales shall be calculated on a Country by Country basis each Year, with the Net Sales for each of Year One, Year Two and Year Three in a given Country in Europe being added to the Net Sales for each of Year One, Year Two and Year Three for all other countries in Europe.

(2) With respect to the Net Sales Goals for each year stated above, in each Year if Net Sales are

(i) at least 90% or higher than the Annual Net Sales Goal, SEARLE will receive the same percentage of the Payment amount. Such

Payment amount will not exceed 100% of the amounts stated in this Section 4.4(c);

- (ii) at least 80 but less than 90% of the Annual Net Sales Goal, SEARLE will receive 80% of the Payment amount;
- (iii) at least 70 but less than 80% of the Annual Net Sales Goal, SEARLE will receive 50% of the Payment amount; and
- (iv) less than 70% of the Annual Net Sales Goal, no payment will be due based upon Annual Net Sales in such Year.

(3) If cumulative Net Sales levels in the United States and Europe are reached in any applicable Year, as described above, in addition to the Payment due with respect to such Year, all Payment(s) or any portion of a Payment for prior Years, if any, which have not already been paid will be paid, regardless of whether the cumulative Net Sales level(s) for such prior Year or Years was/were reached.

(4) The Payment made in any Year plus all Payments made in any preceding Year shall not exceed the Payment detailed above for that Year and all prior Years. As an example, if SEARLE received partial Payments in Years One and Two, upon achieving the Cumulative Net Sales Goals in Year Three, SEARLE will receive the Year Three Payment in full plus the portions of the Year One and Year Two Payments not previously paid by PFIZER.

(d) Immediately upon completion of Phase III, the parties shall negotiate in good faith to determine SGPIs and the PV of SGPIs and the Annual Net Sales Goals. In the event the parties are unable to reach an agreement on all of these matters within twenty-five (25) days after completion of Phase III, each party shall immediately deliver a written statement of their respective positions with respect to SGPIs, the PV of SGPIs, and the Annual Net Sales Goals (a "Statement") to the other party. If PFIZER

shall have timely elected to retain the Rights pursuant to Section 2.5(b), the matter and such Statements shall be submitted to arbitration pursuant to Section 11.2 for determination of SGPIIS, PV of SGPIIS and Annual Net Sales Goals, but the decision of the arbitrators as to the PV of SGPIIS must be no less than that contained in PFIZER's Statement and no more than that contained in SEARLE's Statement. Any milestones paid after the dates specified in Section 4.4(c) shall bear interest at the rate specified in Section 4.6 notwithstanding that a final decision in arbitration has not been rendered by such date.

4.5. Payment Currency. All amounts due under the Agreements shall be paid to the designated party in United States currency. In those cases where the amount due is calculated based upon one (1) or more currencies other than United States Dollars, the amount due shall be calculated using the appropriate exchange rate of such non-United States currencies quoted in The Wall Street Journal, Midwest Edition, at the close of business on the last business day of the calendar month in which, (i) in the case of payments determined by reference to Net Sales, the sales were made, and (ii) in the case of payments determined by reference to an expense, the expense was incurred. For all other payments, the amount due shall be calculated using the appropriate exchange rate of such currencies quoted in The Wall Street Journal, Midwest Edition, at the close of business on the date the payment is due. Notwithstanding the foregoing, SEARLE is willing to discuss with PFIZER alternatives to the foregoing with respect to payments other than those under the U.S. Agreements and the Global Agreement, provided that such alternatives do not result in any additional costs or risks to SEARLE.

4.6. Payments. All payments under this Agreement shall be made, at the election of the paying party, either (i) on or before the due date by electronic transfer in immediately available funds via an ACH (automatic clearing house) mechanism to the respective account designated in writing by each party, or (ii) in immediately available funds transferred to such bank account or accounts as the party receiving payment shall designate in writing at least five (5) Business Days before the payment is due. In the event

payment is made under clause (ii) in the preceding sentence, PFIZER shall notify MONSANTO's Treasurer, or such other party as MONSANTO's Treasurer shall designate in writing, by facsimile transmission as to the date and amount of any payment at least five (5) Business Days prior to such transfer. MONSANTO shall notify PFIZER's Treasurer, or such other party as PFIZER's Treasurer shall designate in writing, by facsimile transmission as to the date and amount of any payment at least five (5) Business Days prior to such transfer. All payments under this Agreement shall bear interest from the date due until paid at a rate equal to three percent (3%) over the prime rate in effect at Citibank, N.A., New York, New York, on the date such payment was due. Payments made under this Article 4 shall not be refundable for any reason or under any circumstances (including the failure to secure an approved NDA for the Product or the Second Generation Product), except for manifest error in the calculation of such payment, provided that nothing contained herein shall in any way prejudice, diminish or otherwise affect any other right, power or privilege of any party under this Agreement.

4.7. Audits and Adjustments. Each party shall have the right, not more than once during any year, to have the books and records of the other party audited by a "Big Six" independent accounting firm of its choosing (as to which firm the other party has no reasonable objection), under appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations under the Agreements (other than with respect to Excepted Matters as defined in Section 11.2(h) which, by their terms, are to be resolved by a party or committee or other specified procedure), including without limitation, the numbers of Details, the reports and payments under Sections 4.2 and 4.3 of this Agreement and Sections 5.3, 6.1, 6.2 and 6.3 of the U.S. Collaboration Agreement and Sections 4.1, 5.1, 5.2 and 5.3 of the U.S. Second Generation Collaboration Agreement and corresponding provisions of the International Agreements. Any such audit shall be conducted no more than once each Year during the term of this Agreement, and for three (3) years thereafter, and upon at

least thirty (30) days' advance notice during normal business hours and in a manner that does not interfere unreasonably with the business of the audited entity. The results of any such audit shall be delivered in writing to each party and shall be final and binding upon the parties, other than manifest error, with respect to the matters set forth therein. Any underpayment or overbilling determined by such audit shall promptly be paid or refunded by the audited party. If the audited party has underpaid or overbilled an amount due under this Agreement by more than five percent (5%), the audited party shall also reimburse the other party for the cost of such audit (with the cost of the audit to be paid by the auditing party in all other cases), plus interest at the interest rate set forth in Section 4.6, from the date of any such underpayment or overpayment. Such accountants shall not reveal to the party seeking verification the details of its review, except for such information as is required to be disclosed under the Agreements, and shall be subject to the confidentiality provisions contained in the Agreements.

If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, the party owing any money hereunder shall pay the same to the party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section 4.7.

4.8. Taxes. Payments under this Agreement or any of the other Agreements shall not be reduced by any taxes, licenses, fees or other withholdings levied upon such payments by any Governmental Authorities of any Country from which a party makes the payment, provided, however, such payment shall be reduced to the extent the payee is entitled to a tax benefit as a result of such payment of taxes, licenses, fees or other withholdings. A payee will be determined to have received a benefit for withholding taxes imposed if, and to the extent, the withholding tax reduces or will reduce a foreign tax otherwise payable. The foreign tax otherwise payable will be determined by taking into account allocable deductions that the payee would have under the relevant foreign tax law. Notwithstanding the foregoing, the payee shall bear withholding taxes to the extent the tax imposed exceeds the tax which otherwise would have been imposed had the payee been

entitled to the benefits of any Income Tax Treaty that the United States has with the jurisdiction from which the payor made payment, except, in the case where the payor makes payment from the United States, the relevant treaty shall be the treaty between the United States and the Netherlands.

## ARTICLE 5

### INDEMNIFICATION

#### 5.1. Indemnification in Favor of PFIZER.

(a) Each of MONSANTO and SEARLE shall indemnify, defend and hold PFIZER PARTIES (as hereinafter defined) harmless from and against any and all Losses (as hereinafter defined) incurred, suffered or sustained by PFIZER PARTIES or to which PFIZER PARTIES become subject, arising out of or resulting from:

- (i) any misrepresentation or breach of any representation, warranty, covenant or agreement made by MONSANTO or SEARLE in this Agreement or any of the other Agreements; or
- (ii) any third party claims, actions, suits, proceedings, liabilities or obligations ("Third Party Claims") arising out of or resulting from:
  - (aa) any misrepresentation or breach of any representation, warranty, covenant or agreement made by MONSANTO or SEARLE in this Agreement or any of the other Agreements; or
  - (bb) the manufacture, use or sale of a Product or Second Generation Product, except for Third Party Claims involving death or bodily injury or any violation of the Act or any infringement of any third party patent rights; or

- (iii) any claim for indemnification by PFIZER which is wrongfully disputed by either MONSANTO or SEARLE.

For purposes of this Article 5, "PFIZER PARTIES" means PFIZER and its Affiliates and their respective agents, directors, officers and employees.

- (b) None of the indemnities in Section 5.1(a) shall apply to the extent that any Loss is primarily the result of any breach of this Agreement or any of the other Agreements by PFIZER or of any negligence, recklessness or willful misconduct of PFIZER PARTIES.

5.2. Indemnification in Favor of SEARLE.

- (a) PFIZER shall indemnify, defend and hold SEARLE PARTIES (as hereinafter defined) harmless from and against any and all Losses incurred, suffered or sustained by SEARLE PARTIES or to which SEARLE PARTIES become subject, arising out of or resulting from:
  - (i) any misrepresentation or breach of any representation, warranty, covenant or agreement made by PFIZER in this Agreement or any of the other Agreements, or
  - (ii) any Third Party Claims arising out of or resulting from:
    - (aa) any misrepresentation or breach of any representation, warranty, covenant or agreement made by PFIZER in this Agreement or any of the other Agreements, or
    - (bb) the negligence, recklessness or willful misconduct of PFIZER PARTIES in connection with PFIZER's performance of this Agreement or any of the other Agreements, or
  - (iii) any claim for indemnification by MONSANTO or SEARLE which is wrongfully disputed by PFIZER.

For purposes of this Article 5, "SEARLE PARTIES" means MONSANTO, SEARLE and their Affiliates and their respective agents, directors, officers and employees.

(b) None of the indemnities in Section 5.2(a) shall apply to the extent the Loss is primarily the result of any breach of this or any of the other Agreements by SEARLE or of any negligence, recklessness or willful misconduct of SEARLE PARTIES.

5.3. Co-Indemnification. Each of MONSANTO and SEARLE shall indemnify, defend and hold PFIZER PARTIES harmless from and against (X) one hundred percent (100%) of the amount of any and all Losses arising out of or resulting from any Third Party Claim arising out of or resulting from the manufacture, use or sale of the Product or Second Generation Product involving death or bodily injury or any violation of the Act or any infringement of any third party patent rights up to and including cumulative Losses from all such Third Party Claims of Two Hundred Fifty Million Dollars (\$250,000,000) (the "Threshold"), and (Y) seventy-five percent (75%) of any such Losses in excess of the Threshold involving death or bodily injury or any violation of the Act and fifty percent (50%) of any such Losses in excess of the Threshold involving infringement of any third party patent rights. PFIZER shall indemnify, defend and hold SEARLE PARTIES harmless from and against twenty-five percent (25%) of the amount of any and all Losses in excess of the Threshold arising out of or resulting from any Third Party Claims arising out of or resulting from the manufacture, use or sale of the Product or Second Generation Product involving death or bodily injury or any violation of the Act, and fifty percent (50%) of any such Losses in excess of the Threshold involving infringement of any third party patent rights. For purposes of this Section 5.3, the Threshold shall apply regardless of whether the indemnifications are made by MONSANTO, SEARLE or a combination thereof. For purposes of this Section 5.3, MONSANTO or SEARLE shall be the "Indemnifying Party" as that term is used in Section 5.6 and MONSANTO or SEARLE shall have full control of any such Third Party Claim as contemplated in Section 5.6, so long as the Litigation Conditions are satisfied. Any

claim by PFIZER for indemnification which could be made under both (X) Section 5.1(a)(i) or 5.1(a)(ii)(aa) and (Y) 5.3 shall be made only under Section 5.3.

5.4. "Losses". For purposes of this Article 5, "Losses" shall mean any and all losses, liabilities, damages, governmental penalties or punitive damages, deficiencies, interest, awards, judgments and settlement amounts paid to third parties and any and all reasonable costs and expenses (including reasonable attorneys' fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened incident to the successful enforcement of this Agreement) in connection therewith.

5.5. Limitation of Damages/Sole Remedy. IN NO EVENT SHALL PFIZER OR MONSANTO OR SEARLE BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY ANY SEARLE PARTIES OR ANY PFIZER PARTIES, RESPECTIVELY, EXCEPT (A) TO THE EXTENT OF ANY SUCH DAMAGES PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM, AND (B) FOR PURPOSES OF INDEMNIFICATION PURSUANT TO SECTION 5.1(a) AND 5.2(a) IN THE EVENT OF AN INTENTIONAL AND WILLFUL BREACH IN BAD FAITH OF ANY COVENANT OR AGREEMENT BY SEARLE OR PFIZER (AS THE CASE MAY BE) OF THIS OR ANY OTHER AGREEMENT. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, INDEMNIFICATION PURSUANT TO THIS ARTICLE 5 SHALL BE THE SOLE AND EXCLUSIVE REMEDY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY) AVAILABLE TO MONSANTO, SEARLE OR PFIZER FOR ANY MISREPRESENTATION UNDER OR BREACH OF THIS AGREEMENT. FOR AVOIDANCE OF DOUBT, ANY DAMAGES INVOLVING RETURN OF MILESTONE PAYMENTS SHALL BE CONSIDERED DIRECT DAMAGES AND THIS SECTION 5.5 SHALL NOT APPLY TO ANY CLAIM BY PFIZER TO RECOVER COMPENSATION AS EXPRESSLY PROVIDED UNDER SECTION 7.4 OF THIS AGREEMENT, SECTIONS 6.4 OR 6.6(a) OF

THE U.S. COLLABORATION AGREEMENT, OR SECTIONS 5.4 OR 5.6 OF THE U.S. SECOND GENERATION COLLABORATION AGREEMENT.

5.6. General Indemnification Procedures.

(a) A party seeking indemnification pursuant to Article 5 (an "Indemnified Party") shall give prompt notice to the party from whom such indemnification is sought (the "Indemnifying Party") of the commencement or assertion of any Third Party Claim (which in no event includes any claims by any PFIZER PARTIES or any SEARLE PARTIES) in respect of which indemnity may be sought hereunder, shall give the Indemnifying Party such information with respect thereto as the Indemnifying Party may reasonably request, and shall not make any admission concerning such Third Party Claim, unless such admission is required by applicable Law or legal process, including in response to questions presented in depositions or interrogatories. Any admission made by the Indemnified Party, except for an admission required by applicable Law or legal process, or the failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the ability of the Indemnifying Party to defend such Third Party Claim is prejudiced thereby. The Indemnifying Party shall have the right, exercisable by written notice to the Indemnified Party within thirty (30) days of receipt of notice from the Indemnified Party of the commencement or assertion of a Third Party Claim, to assume and conduct the defense of such Third Party Claim which involves solely monetary damages, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party, provided that (A) the Indemnifying Party expressly agrees in such notice that, as between the Indemnifying Party and the Indemnified Party, such Third Party Claim is within the scope of and subject to indemnification in accordance with the terms of this Agreement, and (B) solely with respect to SEARLE as the Indemnifying Party where MONSANTO has not agreed to be obligated pursuant to clause (A) above, SEARLE makes reasonably adequate provision to ensure the Indemnified Party of the ability of SEARLE to satisfy the full amount of any adverse monetary judgment

that may result (the conditions set forth in clauses (A) and (B) are collectively referred to as the "Litigation Conditions"). Subject to the satisfaction of the Litigation Conditions, the Indemnifying Party shall have full control of such Third Party Claim, including settlement negotiations and any legal proceedings.

(b) The Indemnifying Party or the Indemnified Party, as the case may be, shall have the right to participate in (but not control), at its own expense, the defense of any Third Party Claim which the other is defending as provided in this Agreement, provided, the Indemnifying Party shall not be liable for any litigation costs or expenses incurred, without its consent, by the Indemnified Party where the action or proceeding is under the control of the Indemnifying Party and the Indemnifying Party is conducting such defense diligently.

(c) The Indemnifying Party, if it shall have assumed the defense of any Third Party Claim as provided in this Agreement, shall not consent to a settlement of, or the entry of any judgment arising from, any such Third Party Claim to the extent such Third Party Claim involves equitable or other non-monetary relief from the Indemnified Party, without the prior written consent of the Indemnified Party. No party shall, without the prior written consent of the other parties, enter into any compromise or settlement which commits the other parties to take, or to forbear to take, any action.

(d) Whether or not the Indemnifying Party chooses to defend or prosecute any Third Party Claim, all the parties hereto shall cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested in connection therewith.

(e) Any indemnification hereunder shall be made net of any insurance proceeds recovered by the Indemnified Party; provided, however, that if, following the payment to the Indemnified Party of any amount under this Article 5, such Indemnified Party recovers any insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall

promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such indemnification payment) to the Indemnifying Party.

## ARTICLE 6

### MANUFACTURING

(a) SEARLE shall have exclusive rights with respect to the manufacture of the Compound, the Second Generation Compound, the Product and the Second Generation Product. The parties shall, however, from time to time review and SEARLE shall consider, with no obligation to agree to, the MSC's recommendations regarding the manufacturing and related processes with respect to the Compound and the Second Generation Compound or Product and the Second Generation Product.

(b) PFIZER shall have the right, at PFIZER's cost, to qualify a manufacturing facility as a backup source of manufacture for the Compound, Second Generation Compound, Product and/or Second Generation Product. Compound, Second Generation Compound, Product and/or Second Generation Product resulting from such qualification activities, which meets the appropriate specifications, will be supplied to SEARLE for commercial use, provided that SEARLE shall have no obligation to make use of such facility and any such use at such facility shall be at SEARLE's sole discretion. PFIZER will be reimbursed for its actual manufacturing cost. SEARLE agrees to make available to PFIZER manufacturing technology required for qualification of backups.

(c) SEARLE shall use all reasonable efforts to supply in a consistent fashion sufficient quantities of Product and Second Generation Product necessary to meet all reasonable and forecasted demands therefor. In the event, however, that SEARLE, through use of its own manufacturing capacity and/or third parties, shall be unable to meet inventory guidelines (as set by CCC), PFIZER may

manufacture Product or Second Generation Product until such time as SEARLE can meet the guidelines.

SEARLE will reimburse PFIZER at PFIZER's actual cost of such Product or Second Generation Product.

## ARTICLE 7

### TERM AND TERMINATION

7.1. Term. This Agreement shall be effective as of the Effective Date and shall continue in force until the expiration of the term or earlier termination of the last of the Agreements (other than this Agreement).

7.2. Termination for Breach. Either party (the "non-breaching party") may terminate this Agreement and any or all of the other Agreements by written notice to the other party (the "breaching party") if the breaching party is in default of any of its material obligations hereunder or under any of the other Agreements and fails to remedy such default within ninety (90) days (thirty (30) days in the case of a payment default) after written notice thereof by the non-breaching party specifying in reasonable detail the nature of such breach.

7.3. Termination upon Change of Control of MONSANTO or SEARLE or Antitrust Bar.

(a) In the event (i) of a Change of Control (as defined in Section 7.5 below) with respect to MONSANTO or SEARLE which results in a significant competitor of PFIZER within the pharmaceutical industry in the major pharmaceutical markets world-wide obtaining control of MONSANTO or SEARLE as described below, upon written notice to MONSANTO and SEARLE within sixty (60) days following the Change of Control or receipt of MONSANTO's notice, as provided in Section 7.5, whichever is later, or (ii) PFIZER seeks to acquire substantially all the assets or stock of a non-Affiliate pharmaceutical company and the existence of the Agreements would, in the legal opinion (without material qualification) of a nationally recognized antitrust counsel, prevent such acquisition due to U.S. antitrust Law, upon ninety

(90) days written notice to MONSANTO and SEARLE together with a copy of the legal opinion by antitrust counsel, PFIZER may terminate all of the Agreements. The effective date of termination shall be the anniversary of the date of PFIZER's notice of termination with respect to clause (i) above, and ninety (90) days following receipt by MONSANTO of PFIZER's notice with respect to clause (ii) above, provided, however, that the non-competition provisions of the other Agreements shall remain in full force and effect for the period ending on the second anniversary date of the effective date of termination, except if such date is after the end of Year Ten, in which case the non-competition provisions will terminate as of such effective date.

(b) If PFIZER terminates the Agreements in the event of a Change of Control under sub-section (a)(i) above, PFIZER shall be entitled to a termination payment equal to the sum of:

- (i) all milestone payments made to SEARLE under the Agreements prior to the effective date of termination;
- (ii) all Development Costs and Promotion Expenses paid to SEARLE under the Agreements prior to the effective date of termination;
- (iii) all internal costs (including field force costs applicable to Details of the Product and Second Generation Product and reasonable overhead), allocable under GAAP to the promotion and/or sale of Product or Second Generation Product and incurred prior to the effective date of termination;
- (iv) PFIZER's cost of net invested capital calculated using a return rate of six and one-half percent (6.5%) compounded annually; and
- (v) all amounts paid by PFIZER to SEARLE pursuant to Article III of the Option Agreement referred to as Exhibit D in Article 9 of the U.S. Second Generation Collaboration Agreement,

less

all payments (based upon Net Sales of Product or Second Generation Product) made to PFIZER pursuant to the Agreements prior to the effective date of termination, plus pre-tax profits earned by PFIZER in Co-Marketing Countries and PFIZER Exclusive Countries ("Payment Received").

For purposes of the above, PFIZER's "net invested capital" at any time shall be the sum of sub-section (b)(i), (ii), (iii) and (v) less its Payment Received.

(c) If the parties are unable to agree upon such termination payment within sixty (60) days of PFIZER's notice under sub-section (a) above, the determination of such payment will be made by a nationally recognized independent certified auditing firm (not then auditing the consolidated books of either MONSANTO or PFIZER and/or their respective Affiliates) selected by the parties, the selection of which shall not be unreasonably withheld or delayed.

(d) The decision of the auditing firm who shall act as experts and not as arbitrators shall be final and binding on the parties (absent manifest error) and not subject to arbitration.

(e) Payment shall be made by MONSANTO to PFIZER within thirty (30) days of the auditing firm's notice to the parties of the termination payment.

(f) PFIZER shall continue to comply with all its marketing, detailing, promotional, clinical and other obligations under the Agreements until the effective date of termination.

#### 7.4 Termination upon Change of Control of PFIZER.

(a) In the event of a Change of Control with respect to PFIZER, MONSANTO may terminate all of the Agreements prior to the expiration of the term upon written notice to PFIZER ("Termination Notice") given within sixty (60) days following the Change of Control or receipt of PFIZER's notice, as provided in Section 7.5, whichever is later. The effective date of termination shall be the anniversary of the date of the Termination Notice.

(b) In such case, PFIZER shall be entitled to compensation calculated to give PFIZER the net present value of PFIZER's interest in the Product, taking into account the co-promotion and license rights granted. The valuation will reflect the cumulative discounted value, utilizing a discount rate of prime (as published in the Mid-West Edition of The Wall Street Journal as of the date of termination) plus 300 basis points, of PFIZER's share of the Product and, if applicable, Second Generation Product earnings from the date of termination to the end of the applicable stated co-promotion or license term. The value of PFIZER's interest in the Product and, if applicable, Second Generation Product so determined shall be the termination compensation payable to PFIZER. Compensation shall not be payable for any product not being marketed as of the date of MONSANTO's Termination Notice (except as otherwise provided in subsection (c) below) or for which PFIZER has elected not to participate in development costs as provided in the Agreements (such as pursuant to Sections 6.5 and 6.6 of the U.S. Collaboration Agreement and/or Sections 5.5 and 5.6 of the U.S. Second Generation Collaboration Agreement). Promptly following the Termination Notice, the parties shall make a good faith attempt to agree upon the compensation due to PFIZER pursuant to the procedure below:

- (i) MONSANTO shall make an offer to PFIZER of such compensation terms.
- (ii) PFIZER shall have thirty (30) days following receipt of such terms in which to accept the terms offered by MONSANTO, or propose to MONSANTO such other terms as PFIZER may elect.
- (iii) If the parties are unable to agree upon such terms within forty-five (45) days of MONSANTO's first offer to PFIZER pursuant to clause (i) above, the determination of such compensation will be submitted to arbitration pursuant to Section 11.2; provided that, the arbitrators must select one of the set of terms as last submitted by each of the parties, without any modification or compromise with respect thereto.

(iv) The compensation determined as provided above, shall be payable in three (3) equal annual installments made at the beginning of each Year (as defined in the U.S. Collaboration Agreement), commencing with the Year beginning after the determination by the arbitrators. The second and third installments will bear interest at the prime rate of interest as announced by Citibank, N.A., New York, New York and in effect at the beginning of each such Year.

(c) In addition to the termination compensation determined as provided above, PFIZER shall be reimbursed for Development Costs paid by PFIZER for any product not being marketed as of the date of MONSANTO's Termination Notice, any Development Costs for studies paid by PFIZER, the results of which are not being used in the market as of the date of MONSANTO's Termination Notice and all milestone payments made with respect to the Second Generation Product, if the Second Product is not being marketed as of the date of MONSANTO's Termination Notice.

7.5. Change of Control. For the purposes of this Article 7, a "Change of Control" shall be deemed to have taken place if (i) a third party, including a "group" as defined in Section 13(d)(3) of the Securities Exchange Act of 1934 but excluding the current directors of PFIZER, MONSANTO or SEARLE, each of which is hereinafter referred to as the "Company", as the case may be, becomes the beneficial owner of shares having fifty percent (50%) or more of the total number of votes that may be cast for the election of directors of the Company; or (ii) as the result of, or in connection with, any cash tender or exchange offer, merger or other business combination, sale of assets or contested election, or any combination of the foregoing transactions (a "Transaction"), (A) the persons who were directors of the Company before the Transaction shall cease to constitute a majority of the Board of Directors of the Company or any successor to the Company, or (B) there is the sale, exchange or other disposition of all or substantially all of the Company's assets to a third party. Within thirty (30) days following a Change of Control of a Company, such Company shall provide notice thereof to the other parties to this Agreement.

7.6. Survival of Obligations. Notwithstanding any termination of this Agreement, (a) neither party shall be relieved of any obligations incurred prior to such termination, and (b) the obligations of the parties with respect to indemnification (Article 5), dispute resolution (Section 11.2), the obligations of the parties with respect to the protection and nondisclosure of Confidential Information (Article 9), as well as any other provisions (including, but not limited to, Section 8.2 of this Agreement and the other Agreements) which by their nature are intended to survive any such termination, shall survive and continue to be enforceable. Upon any termination of this Agreement each party shall promptly return to the other party all written Confidential Information, and all copies thereof, of such other party and PFIZER shall have no further right with respect to, and shall cease all activities related to promotion of the Product and the Second Generation Product.

## ARTICLE 8

### INTELLECTUAL PROPERTY RIGHTS AND LABELING

8.1. Trademark and Corporate Logos. Each party shall retain all right, title and interest in and to its respective corporate logo.

(a) The Product and Second Generation Product shall be promoted and sold under Trademark(s) selected and owned by SEARLE. PFIZER shall have no rights in or to the Trademark(s) or the goodwill pertaining thereto, except that in Countries in which the applicable Law requires PFIZER to own such Trademark(s), PFIZER shall own such Trademark(s), provided that, upon termination or expiration of this and/or the other Agreements, PFIZER shall promptly execute all necessary and/or appropriate documentation to assign such Trademark(s) to SEARLE. In the United States and all other Countries, SEARLE shall own and retain all rights to association of trademark, trade dress, service marks, copyrights or goodwill associated with the Product and Second Generation Product other than PFIZER's company name and logo. PFIZER shall utilize the Trademark(s) only on Promotional Materials or Product-

related or Second Generation Product-related materials approved by SEARLE, for internal use within PFIZER and for the purposes contemplated herein. PFIZER agrees that upon termination or expiration of this Agreement it shall discontinue forthwith all use of the Trademark(s). SEARLE shall use all reasonable efforts to have the Product brand name on the capsules as soon as practicable and to eliminate the names of the parties therefrom.

(b) The parties agree that, subject to the requirements of applicable Laws and approval of Governmental Authorities (if required), if so requested by PFIZER, the SEARLE and PFIZER names shall be given equal exposure and prominence on all package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the Product or Second Generation Product under the U.S. Agreements and the International Collaboration Agreements. Accordingly, PFIZER grants SEARLE the right free of charge to use the PFIZER logo on package inserts, packaging, samples and on all Promotional Materials used or distributed in connection with the Product or Second Generation Product during the respective terms of the International Collaboration Agreements and U.S. Agreements and thereafter (i) for a period of six (6) months with respect to advertising and Promotional Materials, and (ii) for a period of one (1) year with respect to package inserts, packaging, labeling, trade packaging, and samples, or until the inventory of such Product or Second Generation Product and Promotional Materials is exhausted, whichever is earlier, and provided that SEARLE will use diligent efforts to minimize the period during which such logo is used after the term of this Agreement. Notwithstanding the foregoing provisions of this subsection (c), SEARLE shall only be required to use reasonable efforts to include PFIZER's name on materials related to Cox-2 Technology Promotion; provided that PFIZER shall not be obligated to bear, pay or reimburse any cost or expense associated with any Cox-2 Technology Promotion for the materials prepared more than six (6) months after the Effective Date which do not include PFIZER's name in reasonable prominence.

8.2. Ownership.

(a) PFIZER shall have the right, title and ownership in and to New Information that it develops independently from SEARLE ("PFIZER New Information"); provided, however, SEARLE (regardless of whether such PFIZER New Information is patentable) shall be entitled to a non-exclusive, perpetual, irrevocable, royalty-free, fully paid-up world-wide license, including the right to sub-license, of any PFIZER New Information for all uses and purposes. SEARLE shall have the right, title and ownership in and to all other New Information, including any New Information jointly developed by the parties; provided, however, PFIZER (regardless of whether such New Information is patentable), shall be entitled to a non-exclusive, perpetual, irrevocable, royalty-free, fully paid-up, world-wide license, including the right to sub-license, of any such New Information for all uses and purposes, except in connection with the Product, Compound, Second Generation Product or Second Generation Compound or Analogous Products of SEARLE. Notwithstanding anything to the contrary contained herein or any of the other Agreements referred to herein, this Section 8.2(a) shall survive any termination or expiration of this Agreement.

(b) SEARLE shall (i) promptly communicate to PFIZER any New Information, (ii) if applicable, without delay, file patent application(s) with regard to such New Information, and (iii) at PFIZER's request, execute any and all documents necessary to grant the license(s) under such New Information according to Section 8.2(a). PFIZER shall (i) promptly communicate to SEARLE any PFIZER New Information, (ii) if applicable, without delay, file patent application(s) with regard to such PFIZER New Information, and (iii) at SEARLE's request, execute any and all documents necessary to grant the license(s) under such PFIZER New Information according to Section 8.2(a).

8.3. Prosecution and Maintenance of Patents. SEARLE shall make adequate filings for, and prosecute and maintain, all Patent Rights unless SEARLE reasonably believes that any such Patent Right is not material to the matters contemplated in this Agreement. At PFIZER's reasonable request, SEARLE shall advise PFIZER of the status of pending applications, shall provide PFIZER with copies of

documentation concerning such applications and shall consult with PFIZER before taking any action materially affecting the scope of patent coverage relating to the Product or Second Generation Product. SEARLE shall file all applications and take any actions necessary to obtain patent extensions and supplementary protection certificates for Patent Rights where available in the United States, the Co-Promotion Territory and License Territory unless SEARLE reasonably believes that any such Patent Right is not material to the matters contemplated in this Agreement.

8.4. Infringement.

(a) Each party shall promptly inform the other (an "Infringement Notice") if it discovers an infringement by third parties of the Trademarks, Know-How, Patent Rights, or other intellectual property rights related to the Product or Second Generation Product, and shall consult with the other party regarding the necessary and appropriate action. Except as specifically provided below, SEARLE shall have the exclusive right to decide which actions should be taken with respect to enforcing its property rights in the Trademark(s), Know-How and Patent Rights (and shall have full control of such matters, including settlement negotiations and any legal proceedings) (collectively, "IP Enforcement Actions") and, where PFIZER has not elected to Participate (as defined below) in such Enforcement Actions, SEARLE shall be responsible for all costs and expenses (including reasonable attorneys' fees and costs) arising hereafter from or relating thereto and shall be the sole beneficiary of any amounts recovered. Within sixty (60) days following any Infringement Notice, PFIZER shall have the right (but not the obligation) to participate ("Participate") in any IP Enforcement Action and, in the event that PFIZER notifies SEARLE that it elects to Participate in any such IP Enforcement Action, PFIZER shall use all reasonable efforts to cooperate in SEARLE's handling and prosecution thereof and shall contribute fifty percent (50%) of the costs and expenses (including reasonable attorneys' fees and costs) arising from or relating thereto and PFIZER shall be entitled to fifty percent (50%) of any amounts recovered in connection therewith (which recovered amounts shall first be applied, pro rata, to cover costs and expenses of the parties and thereafter

distributed equally). Should SEARLE determine not to pursue any IP Enforcement Action in any PFIZER Exclusive Country within sixty (60) days following any Infringement Notice, PFIZER shall have the right (but not the obligation) to pursue any IP Enforcement Action in such PFIZER Exclusive Country, in which case SEARLE shall use all reasonable efforts to cooperate in PFIZER's handling and prosecution thereof and PFIZER shall be responsible for all costs and expenses (including reasonable attorneys' fees and costs) arising from or relating thereto and shall be the sole beneficiary of any amounts recovered.

(b) In furtherance of Section 8.4(a), PFIZER may elect, within thirty (30) days following the Effective Date, to participate in current and anticipated proceedings between SEARLE and Merck & Co., Inc. regarding SEARLE's cyclooxygenase-2 inhibitor intellectual property rights. In connection therewith, the terms and conditions of Section 8.4(a) shall apply to PFIZER's participation in such proceedings, including the sharing of fees and costs of outside counsel which PFIZER may designate to participate in such proceedings. SEARLE and PFIZER shall establish a committee, consisting of representatives of both parties (including MONSANTO's Associate General Counsel Pharma and PFIZER's General Counsel), for the purpose of consulting with respect to the conduct of such proceedings, and any disagreement shall be resolved by the respective Presidents of SEARLE and PFIZER, with the President of SEARLE having final determination, and any such final determination shall not be subject to arbitration. Any resolution of such proceedings shall be subject to Section 8.5.

8.5 Resolution of Intellectual Property Matters. Notwithstanding anything to the contrary contained in the Agreements, SEARLE shall have the right to resolve any proceeding with Merck & Co., Inc. referenced in Section 8.4(b) by enabling Merck & Co., Inc. and/or its affiliates to market in any country(ies) a cyclooxygenase-2 inhibitor product under any SEARLE intellectual property rights not directly related to the Product or Second Generation Product (the "Resolution"). The terms and conditions of any Resolution shall be referred to the committee and its procedures established under Section 8.4(b). In the event of a Resolution, fifteen percent (15%) of any proceeds received by SEARLE under the

Resolution during the remainder of the Co-Promotion Term under the U.S. Collaboration Agreement shall be provided to PFIZER. To the extent the proceeds of any Resolution includes product(s) rights granted to SEARLE or its Affiliates, the value of such rights for purposes hereof shall be limited to the value of such rights realized during the remainder of the Co-Promotion Term, less fifteen percent (15%) of any costs and expenses (consistent with costs and expenses included within the definitions of Development Costs and Promotion Costs) incurred by SEARLE in the development and exploitation of such product rights.

## ARTICLE 9

### CONFIDENTIAL INFORMATION

9.1. Treatment of Confidential Information. Subject to Section 8.2 during the terms of the Agreements and for ten (10) years after the date on which the last of the Agreements has expired or been terminated, each party hereto shall maintain the Confidential Information (as defined in Section 9.2) of the other party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others (except to its licensees existing as of the Effective Date), or use it for any purpose, other than with respect to the development, manufacture, marketing, promotion, distribution or sale of the Product and Second Generation Product and hereby agrees to exercise its best efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its directors, officers, employees, consultants, subcontractors, licensees or agents.

9.2. “Confidential Information” means the terms and conditions of this Agreement and all materials, trade secrets or other information, including without limitation, any data, proprietary information and materials (whether or not patentable, or protectable as a trade secret) regarding a party's technology, products, business information or objectives, which is disclosed by a party to the other party and which is designated as confidential in writing, or so treated by, the disclosing party. All information disclosed prior to

the Effective Date by SEARLE to PFIZER under or pursuant to the confidentiality agreement between the parties dated November 21, 1997, shall be deemed "Confidential Information" of SEARLE.

9.3. Exceptions. Section 9.1 shall not apply to any Confidential Information disclosed hereunder which:

- (1) was known by the receiving party prior to its date of disclosure to the receiving party as shown by its written records; or
- (2) either before or after the date of the disclosure to the receiving party is lawfully disclosed to the receiving party by sources other than the disclosing party rightfully in possession of the Confidential Information; or
- (3) either before or after the date of the disclosure to the receiving party becomes published or generally known to the public, other than through the sale of Product or Second Generation Product in the ordinary course, through no fault or omission on the part of the receiving party or its Affiliates; or
- (4) is independently developed by or for the receiving party without reference to or reliance upon the Confidential Information; or
- (5) is required to be disclosed by the receiving party to comply with applicable Laws, to defend or prosecute litigation or to comply with governmental regulations, provided that the receiving party provides prior written notice of such disclosure to the other party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure; or
- (6) is disclosed to any third party involved in the manufacture, use or sale of Product or Second Generation Product pursuant to Section 2.4 hereof or, except for PFIZER Confidential Information, any potential marketing partner in Brazil or France.

9.4. Publications. If either party (the "publishing party") desires to disclose any New Information in scientific journals, publications or scientific presentation, the publishing party shall provide the other party an advance copy of any proposed publication relating to New Information prior to submission for publication. Such other party shall have a reasonable opportunity to recommend any changes it believes are necessary to preserve Confidential Information, and the incorporation of such recommended changes shall not be unreasonably refused. If such other party informs the publishing party, within thirty (30) days of receipt of an advance copy of a proposed publication, that such publication in its reasonable judgment could be expected to have a material adverse effect on the commercial value of any Confidential Information which is part of the New Information, the publishing party shall delay or prevent such publication as proposed by the other party. In the case of inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) or application(s) for a certificate of invention on the information involved. In the event of any disagreement between the parties under this Section 9.4, such matter shall be referred to the GCC.

## ARTICLE 10

### REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1. MONSANTO's and SEARLE's Representations. Each of MONSANTO AND SEARLE hereby represents, warrants, covenants and agrees as follows:

(a) Each of MONSANTO and SEARLE has the corporate power and authority to execute and deliver the Agreements and to perform its obligations hereunder and thereunder, and the execution, delivery and performance of each of the Agreements has been duly and validly authorized and approved by proper corporate action on the part of MONSANTO and SEARLE, respectively. Assuming due authorization, execution and delivery on the part of PFIZER, each of the Agreements constitutes a legal, valid and binding obligation of MONSANTO and SEARLE, enforceable against each of MONSANTO and SEARLE, respectively, in accordance with its respective terms, except as the enforceability thereof

may be limited by applicable bankruptcy, insolvency, reorganization or other similar laws of general application relating to creditors' rights.

(b) As of the date hereof, the execution and delivery of the Agreements by each of MONSANTO and SEARLE and the performance by each of MONSANTO and SEARLE contemplated hereunder and thereunder will not, subject to the receipt of the permits, authorizations, consents and clearances to which reference is made in paragraph (c) below, violate any applicable Laws.

(c) As of the date hereof, neither the execution and delivery of this Agreement nor the performance hereof by either MONSANTO or SEARLE requires either MONSANTO or SEARLE to obtain any permits, authorizations or consents from any Governmental Authority (except for manufacturing, marketing and Price Approvals from Governmental Authorities with respect to the Product and Second Generation Product and any approvals or clearances of any Governmental Authorities concerned with the administration or enforcement of antitrust or competition Laws (including the Commission of the European Union)) or from any other Person, and such execution, delivery and performance will not result in the breach of or give rise to any termination of any agreement or contract to which either MONSANTO or SEARLE may be a party and which relates to the Product or the Second Generation Product, where the failure to obtain such permit, authorization or consent, or the occurrence of such breach or termination, would have a material adverse effect on either the Product or the Second Generation Product or the ability of either MONSANTO or SEARLE to perform their respective obligations under the Agreements.

(d) Exhibit 1.53 contains a correct and complete list of all patents and trademarks which (x) are pending, applied for, granted or registered in any country or jurisdiction, (y) are either owned by or licensed to SEARLE or any of its Affiliates, and (z) directly relate to the Compound, the Second Generation Compound, the Product or the Second Generation Product as each of them exists as of the date hereof. SEARLE owns or possesses adequate licenses or other valid rights to use (without the making of any payment to others or the obligation to grant rights to others in exchange) all patents, patent

rights, trademarks applications and Know-How now known by SEARLE and MONSANTO as necessary to manufacture, distribute, use and sell the Compound and the Product (collectively, "Intellectual Property"). With respect to the Product, SEARLE does not use any Intellectual Property pursuant to a license from a third party, nor does it license any Intellectual Property to a third party in the Territory, except as specifically indicated in Exhibit 1.53, which contains a correct and complete list of all such licenses, and SEARLE is not in breach of any such licenses. All of the patents listed in Exhibit 1.53 are, to the knowledge of MONSANTO and SEARLE, valid and in full force and effect as of the date of this Agreement, are held of record in the name of SEARLE, free and clear of all liens, encumbrances and other claims, and are not subject to any pending cancellation or reexamination proceeding or any other pending proceeding challenging their extent or validity. SEARLE is the applicant of record in all patent applications and all applications for trademark listed in Exhibit 1.53, and no notice of opposition, interference or refusal to register has been received in connection with any such application. To the knowledge of MONSANTO and SEARLE, the claims included in such patent applications relate to patentable subject matter, and neither MONSANTO nor SEARLE is aware of any valid reason why claims of a reasonable scope would not be allowed to issue in accordance with normal prosecution with the applicable patent offices.

(e) As of the date hereof, except as specifically set forth on Exhibit 1.53, to the knowledge of MONSANTO and SEARLE, the manufacture, use or sale of the Product for osteoarthritis and rheumatoid arthritis clinical indications does not infringe any valid patents of third parties, and, to the knowledge of MONSANTO and SEARLE, no third party is infringing in the Territory any of the issued patents listed in Exhibit 1.53.

(f) Except as specifically set forth in Exhibit 1.53, as of the date hereof, there are no actions, suits, proceedings or claims, pending against SEARLE or any of its Affiliates, or, to the knowledge of SEARLE, threatened in writing against SEARLE or any of its Affiliates, at law or in equity, or before or by any Governmental Authority, relating to the Compound, the Second Generation Compound or the Product

or the Second Generation Product or the manufacture, marketing, distribution, use or sale thereof contemplated under the Agreements. There are no investigations of public record pending or, to SEARLE's knowledge, any investigations ongoing or threatened in writing against SEARLE or any of its Affiliates, at law or in equity, or before or by any Governmental Authority relating to the Compound, the Second Generation Compound or the Product or the Second Generation Product or the manufacture, marketing, distribution, use or sale thereof contemplated under the Agreements or which would otherwise materially adversely affect SEARLE's ability to perform its obligations hereunder.

(g) SEARLE covenants that the NDA to be filed with the FDA and all amendments thereto will be prepared in accordance with all applicable requirements of the Act.

(h) Insofar as SEARLE is aware, SEARLE has heretofore disclosed to PFIZER all material information known to SEARLE with respect to the safety and effectiveness of the Product or the Second Generation Product or human risk factors relating thereto, as well as all material pre-clinical and non-clinical and clinical data; no such information has been falsified as to which SEARLE is aware or after reasonable investigation should have been aware.

(i) SEARLE covenants that during the term of this Agreement it shall carry out the detailing, promotion, marketing and sale of the Product and the Second Generation Product and its other obligations or activities hereunder in material compliance with generally accepted pharmaceutical industry practices and all applicable Laws.

(j) SEARLE covenants that the Product and the Second Generation Product to be distributed by SEARLE during the term of this Agreement will, at the time of shipment by or on behalf of SEARLE, not be misbranded or adulterated under the terms of the Act. The Product and the Second Generation Product shall meet SEARLE's then-current specifications, which specifications shall comply with all applicable current good manufacturing practices, applicable requirements set forth in the IND, NDA,

or supplement for the Product or the Second Generation Product and any other Law applicable to the manufacture of the Product or the Second Generation Product for commercial distribution.

(k) Each of MONSANTO and SEARLE acknowledges that PFIZER is relying, and is entitled to rely, on the foregoing representations, warranties and covenants.

10.2. PFIZER's Representations. PFIZER hereby represents, warrants, covenants and agrees as follows:

(a) PFIZER has the corporate power and authority to execute and deliver the Agreements and to perform its obligations hereunder and thereunder, and the execution, delivery and performance of each of the Agreements has been duly and validly authorized and approved by proper corporate action on the part of PFIZER. Assuming due authorization, execution and delivery on the part of each of MONSANTO and SEARLE, each of the Agreements constitutes a legal, valid and binding obligation of PFIZER, enforceable against PFIZER in accordance with its respective terms, except as the enforceability thereof may be limited by applicable bankruptcy, insolvency, reorganization or other similar laws of general application relating to creditors' rights.

(b) As of the date hereof, the execution and delivery of the Agreements by PFIZER and the performance by PFIZER contemplated hereunder and thereunder will not, subject to the receipt of the permits, authorizations, consents and clearances to which reference is made in paragraph (c) below, violate any applicable Laws.

(c) As of the date hereof, neither the execution and delivery of this Agreement nor the performance hereof by PFIZER requires PFIZER to obtain any permits, authorizations or consents from any Governmental Authority (except for manufacturing, marketing and Price Approvals from Governmental Authorities with respect to the Product and Second Generation Product and any approvals or clearances of any Governmental Authorities concerned with the administration or enforcement of antitrust or competition Laws (including the Commission of the European Union)) or from any other Person, and such execution,

delivery and performance will not result in the breach of or give rise to any termination of any agreement or contract to which PFIZER may be a party and which relates to the Product or the Second Generation Product, where the failure to obtain such permit, authorization or consent, or the occurrence of such breach or termination, would have a material adverse effect on either the Product or the Second Generation Product or the ability of PFIZER to perform its obligations under the Agreements.

(d) As of the date hereof, there are no actions, suits, proceedings or claims, pending against PFIZER or any of its Affiliates, or, to the knowledge of PFIZER, threatened in writing against PFIZER or any of its Affiliates, at law or in equity, or before or by any Governmental Authority relating to the Compound, the Second Generation Compound or the Product or the Second Generation Product or the manufacture, marketing, distribution, use or sale thereof contemplated under the Agreements. There are no investigations of public record pending or, to PFIZER's knowledge, any investigations ongoing or threatened in writing against PFIZER or any of its Affiliates, at law or in equity, or before or by any Governmental Authority relating to the Compound, the Second Generation Compound or the Product or the Second Generation Product or the manufacture, marketing, distribution, use or sale thereof contemplated under the Agreements or which would otherwise materially adversely affect PFIZER's ability to perform its obligations hereunder.

(e) As of the date hereof, PFIZER has not knowingly withheld any information from sources other than SEARLE which would be material to SEARLE in making SEARLE's representations in Sections 10.1(d) and (e), and PFIZER has no knowledge that any representation made by SEARLE in Section 10.1(d) or (e) is incorrect or misleading.

(f) PFIZER covenants that during the term of this Agreement it shall carry out the detailing, promotion, marketing and sale of the Product and the Second Generation Product and its other obligations or activities hereunder in material compliance with generally accepted pharmaceutical industry practices and all applicable Laws.

(g) PFIZER acknowledges that each of MONSANTO and SEARLE is relying, and is entitled to rely, on the foregoing representations, warranties and covenants.

10.3. Product and Second Generation Product. For purposes of the representations and warranties contained in Section 10.1 and 10.2, the term "Product" and the term "Second Generation Product" mean, respectively, the Product and the Second Generation Product as each of them exists as of the date hereof and neither term shall include any reference to any Combination Product.

## ARTICLE 11

### MISCELLANEOUS

11.1. Governing Law. This Agreement shall be governed by and interpreted in accordance with the internal laws of the State of New York excluding its rules governing conflicts of laws and the U.N. Convention on the International Sale of Goods.

11.2. Dispute Resolution. If there shall be a dispute between the parties arising out of or in connection with the validity, interpretation, performance, enforcement or arbitrability of this Agreement or any of its terms or any claim arising out of or in connection with one or more of the Agreements, other than with respect to Excepted Matters (as defined below), PFIZER and SEARLE shall refer the dispute to their respective Chief Operating Officers. If such individuals are unable to resolve the matter within thirty (30) days after the referral, then either party may submit the dispute for final resolution to an arbitration panel consisting of three (3) arbitrators who have significant legal or business experience in pharmaceutical licensing matters selected as follows: MONSANTO shall select one such qualified arbitrator, and PFIZER shall select one such qualified arbitrator, and the two arbitrators so appointed shall select a third such qualified arbitrator. The third arbitrator shall be the presiding arbitrator. In the event either MONSANTO or PFIZER shall have failed to select an arbitrator as provided above within fifteen (15) Business Days after either MONSANTO or PFIZER has selected its arbitrator or the two arbitrators so selected shall fail to

agree on a third arbitrator as provided above, such arbitrator shall be selected by the Washington, D.C.

Office of the American Arbitration Association as appointing authority.

(a) The place of arbitration shall be Washington, D.C.

(b) Except as provided in this Agreement, the arbitration procedure set forth in this Section 11.2 shall be the sole and exclusive means of settling or resolving any dispute referred to in this Section 11.2. The arbitration shall be conducted in accordance with the UNCITRAL Arbitration Rules then in effect, as modified herein.

(c) Within thirty (30) days after the third (3rd) and presiding arbitrator has been appointed, the parties shall exchange all documents in their respective possession relevant to the issues in dispute. At least fifteen (15) Business Days prior to the first (1st) scheduled hearing date, the parties shall identify the witnesses that they intend to present at the arbitration hearing and the documentation on which they intend to rely. The parties shall use their best efforts to conclude the arbitration hearings within six (6) months following the appointment of the third (3rd) and presiding arbitrator. The arbitrators shall issue their decision (including grounds and reasoning) in writing no later than sixty (60) days following the conclusion of the last arbitration hearing.

(d) The award of the arbitrators shall be final and binding on the parties and may be presented by any of the parties for enforcement in any court of competent jurisdiction and the parties hereby consent to the jurisdiction of such court solely for purposes of enforcement of this arbitration agreement and any order or award entered therein. In any such enforcement action, irrespective of where it is brought, none of the parties will seek to invalidate or modify the decision of the arbitrators or otherwise to invalidate or circumvent the procedures set forth in this Section 11.2 as the sole and exclusive means of settling or resolving such dispute.

(e) The fees of the arbitrators and the other costs of such arbitration (including without limitation the award of attorneys' fees to the prevailing party) shall be paid and borne as the arbitrators determine.

(f) Notwithstanding anything to the contrary in the UNCITRAL rules and procedures or in this Section 11.2, either party may, without waiving any remedy under this Agreement, seek from any court of competent jurisdiction any interim or provisional relief, including without limitation orders of injunction, specific performance or other equitable relief, that is necessary to protect the rights or property of that party, pending the arbitrators' determination of the merits of the dispute.

(g) Provided the Agreements have not terminated, the parties covenant to continue the performance under the Agreements in accordance with the terms thereof, pending the resolution of the dispute by their respective Chief Operating Officers or the award of the arbitrators (as the case may be).

(h) For purposes of this Section 11.2, Excepted Matters are defined as all matters with regard to which a Committee, the auditors, or one of the parties has the final decision making authority, including but not limited to matters to be determined pursuant to Sections 3.1, 3.2, 4.4, 4.7, 8.5 or Article 6 of this Agreement or Sections 6.4, 6.5, 6.6 or 7.2 of the U.S. Collaboration Agreement or Sections 5.4, 5.5 or 5.6 of the U.S. Second Generation Collaboration Agreement and any corresponding provisions in the International Agreements.

11.3. Waiver. Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any succeeding breach of the same or any other provision. No delay or omission by a party to exercise or avail itself of any right, power or privilege that it has or may have hereunder shall operate as a waiver of any right, power or privilege by such party. No waiver shall

be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

11.4. Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address below and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable international express courier service; or (d) sent by facsimile transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (five, if international) Business Days after it is sent by registered or certified air mail, return receipt requested, postage prepaid, one (two, if international) Business Days after it is sent via a reputable international express courier service, or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is on a Business Day; otherwise, on the next Business Day following such transmission).

Notices to PFIZER: Pfizer Inc.  
235 East 42nd Street  
New York, New York 10017-5755  
Attention: President, PFIZER Pharmaceuticals Group

with a copy to: Senior Vice President and General Counsel

Notices to SEARLE: G.D. Searle & Co.  
5200 Old Orchard Road  
Skokie, Illinois 60077  
Attention: Chief Executive Officer

with a copy to:

General Counsel  
G.D. Searle & Co.  
5200 Old Orchard Road  
Skokie, Illinois 60077

Either party may change its address by giving notice to the other party in the manner provided above.

11.5. Entire Agreement. This Agreement (including Exhibits) together with the other Agreements and the letter agreement attached as Exhibit 11.5 contains the complete understanding of the parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto. No waiver, alteration or modification of any provision hereof shall be binding unless made in writing and signed by the parties.

11.6. Headings. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.

11.7. References to Dollars. All references to Dollars in the Agreements refer to the United States Dollars.

11.8. Severability. If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction because it is invalid or conflicts with any law of any relevant jurisdiction, or is objected to by the European Commission, the validity of the remaining provisions shall not be affected. The parties shall negotiate a substitute provision that, to the extent possible, accomplishes the original business purpose.

11.9. Registration and Filing of the Agreements. To the extent, if any, that a party concludes in good faith that it is required to file or register any of the Agreements or a notification thereof with any Governmental Authority, including without limitation the U.S. Securities and Exchange Commission, or the U.S. Federal Trade Commission, or the European Commission (the "Commission"), in accordance with applicable Laws, such party may do so. The other party shall cooperate in such filing or notification and shall execute all documents reasonably required in

connection therewith. In such situation, the parties will request confidential treatment of sensitive provisions of the Agreements, to the extent permitted by Law. The parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to the Agreements, and shall cooperate to respond to any request for further information therefrom. Without limiting the foregoing, the parties agree to make all necessary filings required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, to cooperate with each other so as to comply therewith on a timely basis in light of the provisions of the Agreements. In addition, the parties hereby agree to notify jointly in due course, this Agreement and the International Agreements to the Commission for the purpose of obtaining negative clearance or, if the Commission deems the International Agreements to come within Article 85(1) of the Treaty of Rome, an exemption under Article 85(3) of the Treaty of Rome therefor. In this respect, it is further agreed as follows:

- (a) The parties shall cooperate jointly towards the preparation and submission of forms and materials required to notify the International Agreements, including such materials as are reasonably required or requested by the Commission pursuant to such notification;
- (b) The parties shall use all reasonable endeavors to obtain from the Commission confirmation in the form of a comfort letter or, if this is not forthcoming, a formal decision, to the effect that the International Agreements merit a negative clearance as aforesaid or an exemption under Article 85(3);
- (c) If, arising out of such notification, the Commission requires the International Agreements to be changed in any respect, the parties shall negotiate in good faith such changes to as to reflect as nearly as possible the original intentions of the parties; and

(d) Each party shall be responsible for its own legal and other external costs associated with the notification contemplated herein.

11.10. Assignment. Except as otherwise provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by a party without the prior written consent of PFIZER in the case of any assignment by MONSANTO or SEARLE; or MONSANTO, in the case of an assignment by PFIZER, except, in whole or in part, to an Affiliate of the assigning party or to any other party who acquires all or substantially all of the business of the assigning party by merger, sale of assets or otherwise, so long as such Affiliate or other party remains bound by the terms of all the Agreements with respect to which such assignee has been assigned any rights or obligations. The assigning party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void. In the event MONSANTO is no longer an Affiliate of SEARLE, MONSANTO shall be released from all obligations under this and the other Agreements, provided that another Affiliate of SEARLE, which has equal credit standing as MONSANTO, shall assume all of MONSANTO's obligations under this and the other Agreements.

11.11. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

11.12. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

11.13. Force Majeure. In the event of strikes, lock-outs or other industrial disturbances, rebellions, mutinies, epidemics, landslides, lightning, earthquakes, fires, storms, floods, sinking, drought, civil disturbances, explosions, acts or decisions of duly constituted municipal, state or national governmental authorities or of courts of law, as well as impossibility to obtain equipment,

supplies, fuel or other required materials, in spite of having acted with reasonable diligence, or by reason of any other causes, which are not under the control of the party requesting the abatement of performance, or causes due to unexpected circumstances which may not be possible to eliminate or overcome with due diligence by such party ("Force Majeure"), the parties agree that, if either of them find themselves wholly or partially unable to fulfill their respective obligations in any of the Agreements by reasons of Force Majeure, the party affected shall advise the other party in writing of its inability to perform giving a detailed explanation of the occurrence of the event which excuses performance as soon as possible after the cause or event has occurred. If said notice is given, the performance of the party giving the notification, except the payment of funds, shall be abated, and any time deadlines shall be extended, for so long as performance may be prevented by such event of Force Majeure. Except for the payment of funds that are due and payable, neither party shall be required to make up any performance that was prevented by Force Majeure.

11.14. Non-Solicitation of Employees. During the term of this Agreement, neither party shall, directly or indirectly, recruit or solicit any employee of the other party with whom it has come into contact or interacted for the purposes of the performance of this Agreement without the prior written consent of the other party, except pursuant to general solicitations not targeted at such employees.

11.15. Publicity. Neither party shall originate any news release or other public announcement, written or oral, relating to the Agreements without the prior written approval of the other party except as otherwise required by Law. Such approval shall not be unreasonably withheld.

11.16. No License. PFIZER shall have no rights in or to any Patent Rights, Trademark, Know-How, SEARLE's Confidential Information, or New Information except as expressly set forth in the Agreements. SEARLE shall have no rights in or to any of PFIZER's patents, patent

applications, trademarks, tradenames, know-how or PFIZER Confidential Information or other intellectual property of PFIZER, except as expressly set forth in the Agreements.

11.17. Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any third party, including, without limitation, any creditor of either party hereto. No such third party shall obtain any right under any provision of the Agreements or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either party hereto.

11.18. Relationship of the Parties. Each party shall bear its own costs incurred in the performance of its obligations under the Agreements without charge or expense to the other except as expressly provided in the Agreements. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or for any employee compensation or benefits of the other party's employees. No employee or representative of a party shall have any authority to bind or obligate the other party to the Agreements for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other party without said party's approval. For all purposes, and notwithstanding any other provision of the Agreements to the contrary, PFIZER's legal relationship under the Agreements to SEARLE shall be that of independent contractor. Nothing in the Agreements shall be construed to establish a relationship of co-partners or joint venturers between the parties.

11.19. Limitation on Disclosure. Notwithstanding any provision of any of the Agreements which might otherwise be to the contrary, SEARLE shall have no obligation to disclose scientific, marketing or other commercial information related to the Product's or Second Generation Product's development, manufacture or sale in Japan except with respect to adverse event reporting pursuant to Exhibit 11.19.

11.20. Conflict with Other Agreements. The terms of this Agreement shall prevail in case of conflict or inconsistency with the terms of any of the other Agreements.

IN WITNESS WHEREOF, the parties have signed the Agreements as of the Effective Date.

PFIZER INC.

  
By: HENRY A. MCKINNELL, Ph.D.  
Title: EXECUTIVE VICE PRESIDENT

G. D. SEARLE & CO.

  
By: R. De Schutter  
Title: CEO

MONSANTO COMPANY

  
By: R. De Schutter  
Title: Vicki Cipriano

## **EXHIBIT 1.8 - Co-Marketing Countries**

**EXHIBIT 1.8**

# Co-Marketing Countries

**Europe**

*Greece*

*Italy*

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02/02/1998

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**EXHIBIT 1.11 - Co-Promotion Countries**

**EXHIBIT 1.11**

## Co-Promotion Countries

### Americas

Argentina  
Brazil  
Canada  
Chile  
Colombia  
Costa Rica  
El Salvador  
Guatemala  
Honduras  
Mexico  
Nicaragua  
Panama  
Peru  
Venezuela

### Europe

Belgium  
Czech Republic  
Denmark  
Finland  
France  
Germany  
Hungary  
Ireland  
Luxembourg  
Netherlands  
Norway  
Poland  
Portugal  
Russia  
Slovakia  
Spain  
Sweden  
Switzerland  
Turkey  
Ukraine  
United Kingdom

### Africa/Middle East

India  
Saudi Arabia  
South Africa/Zimbabwe

### Asia/Pacific

Australia  
China  
Hong Kong  
Indonesia  
Korea  
Malaysia  
Philippines (JV)  
Singapore  
Taiwan  
Thailand

05/04/1998

**EXHIBIT 1.19 - Detail Presentations**

EXHIBIT 1.19GROUP PRESENTATIONS

Product presentations by PFIZER or SEARLE personnel, as the case may be, devoted primarily to a Product, may be made to licensed prescribers in group situations. Such presentations may be through speaker programs, dinner and lunch programs, symposia, and other programs the nature of which has been approved by the CCC. In calculating the number of Details resulting from such group presentations, each licensed prescriber participating in such presentations will be considered as one(1) Detail. It is understood that for presentations held by multiple personnel of PFIZER or SEARLE, as the case may be, or jointly by PFIZER and SEARLE personnel, the total number of Details credited to each party shall be calculated as follows: For such group presentations conducted by either SEARLE or PFIZER without the other party, the total number of Details credited for such party shall be equal to the total number of licensed prescribers present at any such group presentation regardless of the number of such party's representatives conducting such presentation. For example if two PFIZER representatives conduct a presentation for ten licensed prescribers, the total number of Details credited to PFIZER shall be ten, not twenty. If SEARLE and PFIZER jointly conduct such a group presentation, each party shall be credited with a number of Details equal to fifty percent of the number of licensed prescribers present at such presentation, unless otherwise agreed in advance between the parties. For example, if SEARLE personnel and PFIZER personnel jointly conduct such a group presentation, each party shall be credited with a number of Details equal to 50% of the number of attending licensed prescribers. If, however, prior to such presentation, it is determined that PFIZER or SEARLE will assume more responsibility than the other with respect to such presentation, the parties may agree in advance to credit such party with a greater number of Details than the other party. It is understood that for symposia and other group presentations which contain full presentations on a Product together with other products, the number of Details for such presentations shall be accounted for as provided above.

## EXHIBIT 1.53 - Patents

EXHIBIT 1.53

TABLE 1  
Celecoxib - USA ISSUED PATENTS

Appln. No.	Filing Date	Priority Appln.	Filing Date	Patent No.	Issued
08/160,594	11/30/93	-	-	5,466,823	11/14/95
08/223,629	04/06/94	08/160,594	11/30/93	5,521,207	05/28/96
08/457,059	06/01/95	08/223,629	04/06/94	5,563,165	10/08/96

EXHIBIT 1.53 (cont.)

TABLE 2  
Celecoxib - USA PENDING APPLICATIONS

<u>Appn. No.</u>	<u>Filing Date</u>	<u>Priority Appn.</u>	<u>Filing Date</u>
08/648,113	05/21/96	08/223,629	04/06/94
08/534,757	09/27/95	08/223,628	04/06/94
08/957,345	10/24/97	08/648,113	05/21/96
 Method of Preparing celecoxib			
08/867,754	06/03/97	08/449,975	05/25/95
 Method of Treating neoplasia			
08/949,922	10/14/97		
 Method of Treating angiogenesis			
08/974,201	11/19/97		
 Method of Treating dementia			
60/43916	04/03/97		
 Method of treating cardiovascular diseases			
60/44626	04/18/97		

EXHIBIT 1.53 (cont.)

TABLE 3  
Celecoxib Ex-USA Patent Applications

Country	Appn. No.	Filing Date	Priority Appn.	Filing Date	Patent No.	Issued
BRAZIL	PI1100406-1	05/02/97	08/160,594	11/30/93		
BRAZIL	PI1100407-0	05/02/97	08/223,629	04/06/94		
AUSTRALIA	11714/95	11/14/94				
CANADA	2,177,576	11/14/94				
CZECH	94194833.1	11/14/94				
EPO	PV1503-96	11/14/94				
FINLAND	95902444.9	11/14/94				
HUNGARY	962249	11/14/94				
JAPAN	P9601455	11/14/94				
KOREA, SO	515611/95	11/14/94				
MEXICO	96-702677	11/14/94				
NEW ZEALAND	949255	11/29/94				
NORWAY	276885	11/14/94				
POLAND	P962184	11/14/94				
RUMANIA	P-314695	11/14/94				
RUSSIA	96-01100	11/14/94				
SO AFRICA	96115039	11/14/94				
TAIWAN	94/9418	11/28/94				
	84104854	05/16/95				
Method of Preparing celecoxib						
AUSTRALIA	58736/96	05/23/96		08/449,975		05/25/95
BRAZIL		05/23/96				
CANADA		05/23/96				
CHINA		05/23/96				
CZECH	PV3689-97	05/23/96				
EPO		05/23/96				
JAPAN	535858/96	05/23/96				
KOREA, SO	97-708441	05/23/96				
MEXICO	979065	05/23/96				
NEW ZEALAND	308875	05/23/96				
NORWAY	P975387	05/23/96				
POLAND	P323492	05/23/96				
RUMANIA		05/23/96				
RUSSIA		05/23/96				

EXHIBIT 1.53 (cont.)

TABLE 3 (cont.)  
Celecoxib Ex-USA Patent Applications

<u>Country</u>	<u>Appln. No.</u>	<u>Filing Date</u>	<u>Priority Appln.</u>	<u>Filing Date</u>	<u>Patent No.</u>	<u>Issued</u>
Method of Treating neoplasia						
ARGENTINA	97/01/04767	10/15/97			60/028,494	10/15/96
PCT	US97/18670	10/15/97			"	"
PHILIPPINES	I-58185	10/14/97			"	"
TAIWAN	86115025	10/14/97			"	"

EXHIBIT 1.53 (cont.)

TABLE 4  
2nd Generation USA ISSUED PATENTS

Appln. No.	Filing Date	Priority Appln.	Filing Date	Patent No.	Issued
08/473,884	06/07/95	08/387,680	02/13/95	5,633,272	05/27/97

EXHIBIT 1.53 (cont.)

TABLE 5  
2nd Generations - USA PENDING APPLICATIONS

<u>Appln. No.</u>	<u>Filing Date</u>	<u>Priority Appln.</u>	<u>Filing Date</u>
08/894,124	08/11/97	08/473,884	06/07/95
08/702,417	08/13/96	US/PCT96/01869	02/12/96
08/801,768	02/18/97	08/473,884	06/07/95
Polymorph			
	08/909,512	08/12/97	

EXHIBIT 1.53 (cont.)

TABLE 6  
2<sup>nd</sup> Generation Ex-USA Patent Applications

Country	Appl. No.	Filing Date	Priority Appln.	Filing Date	Patent No.	Issued
AUSTRALIA	48671796	02/12/96	"	08/473,884	06/07/95	"
BRAZIL	P19607035-8	02/12/96	"	"	"	"
CANADA		02/12/96	"	"	"	"
CHINA	96193240-6	02/12/96	"	"	"	"
CZECH	PV2546-97	02/12/96	"	"	"	"
EPO	96904614.2	02/12/96	"	"	"	"
FINLAND	973292	02/12/96	"	"	"	"
JAPAN	525057/96	02/12/96	"	"	"	"
KOREA SO	97-705576	02/12/96	"	"	"	"
NEW ZEALAND	302586	02/12/96	"	"	"	"
NORWAY	P973711	02/12/96	"	"	"	"
POLAND	P321814	02/12/96	"	"	"	"
RUMANIA	97-01522	02/12/96	"	"	"	"
RUSSIA	97115452	02/12/96	"	"	"	"
SO AFRICA	96/1150	02/13/96	"	"	"	"
TAIWAN	85109684	08/09/96	"	"	"	"
Polymorph						
ARGENTINA	97/01/03706	08/14/97	"	60/024,378	08/12/96	"
PCT	US97/15126	08/12/97	"	"	"	"
PHILIPPINES	"	"	"	"	"	"
SO AFRICA	97/7314	08/14/97	"	"	"	"
TAIWAN	86111783	10/14/97	"	"	"	"

EXHIBIT 1.53

Third-Party Patent

Searle has been notified by the University of British Vancouver of a licensing opportunity on United States Patent 5,192,573, and its foreign equivalents, entitled "ANTI-RHEUMATOID ARTHRITIC DRUGS IN THE TREATMENT OF DEMENTIA".

**EXHIBIT 1.53**

**Trademark Applications**

<u>Trademark</u>	<u>Country</u>
CELEBRA	Argentina
CELEBRA	Australia
CELEBRA	Brazil
CELEBRA	Canada
CELEBRA	European Community
	Austria
	Belgium
	Denmark
	Finland
	France
	Germany
	Greece
	Ireland
	Italy
	Luxemburg
	Netherlands
	Portugal
	Spain
	Sweden
	United Kingdom
CELEBRA	Japan
CELEBRA	Mexico
CELEBRA	United States

**EXHIBIT 1.55 - Phase II and Phase III**

EXHIBIT 1.55

Before it is proposed that Phase III development be undertaken for one of the "second generation" candidates, sufficient studies and planning will have been carried out to meet the criteria specified below which define "end of Phase II":

Clinical

- Clinical Pharmacology
  - Single and multiple dose volunteer studies complete, pharmacokinetic parameters known.
  - Major interactions identified: food, methotrexate, anticoagulants.
  - PK variability due to gender and age characterized.
  - CYP450 metabolizing enzymes identified.
  - Metabolic pathways identified in man (ADME study completed).
  - Full evaluation of COX-1 and COX-2 inhibition in man (PK-PD correlations, effects of the agent on platelet function, renal prostaglandins, appropriate ex-vivo testing).
  - Endoscopy study in normal volunteers completed..
  - Plan for clinical pharmacology package to support filing in place.
- Safety and efficacy testing
  - Primary indications for Phase III defined and efficacy demonstrated for primary indications.
  - Optimal doses for Phase III selected.
  - Active comparative agents for Phase III selected based on global considerations (including marketed COX-2 inhibitors, if appropriate).
  - If chronic indications considered: Renal safety characterized for a period 8-12 weeks, using intended Phase III doses and employing specific tests for glomerular and tubular function.

Drug Safety Evaluation

- Genetic toxicology completed.
- Preliminary reports available for 1-6 month chronic studies reported (appropriate duration to support intended chronicity of use).
- Reproductive toxicology studies ("segments") I (fertility in rats) and II (teratology in rats and rabbits) completed.
- Plan for long term carcinogenicity studies in place.

EXHIBIT 1.55(cont.)

Developmental Research

- Appropriate CMC section in place to support Phase III
  - Commercial dosage form(s) and synthetic routes defined for US, Europe, Japan, ROW
  - Refined cost of goods analysis in collaboration with manufacturing
  - Plan in place for CMC section for filing
- Adequate supplies for Phase III program (drug in question, active comparators, placebo) being prepared

Regulatory

- End of Phase II meeting with FDA, European authorities, Japan, and ROW as appropriate completed or planned
- Identification of any outstanding issues with any key regulatory authority and appropriate strategy to address issue developed

Summary strategic plan which includes:

- Overall cost of development through filing
- List of all planned clinical and pre-clinical studies up to the time of NDA filing, with anticipated costs
- Commercial assessment of primary indications

The following definition shall be used for "end of Phase III" for the "second generation" COX-2 inhibitors:

- Database closed on all pivotal Phase III and long-term safety studies. Draft tables containing results of these studies available for review.

**EXHIBIT 1.56 - PFIZER Exclusive Countries**

EXHIBIT 1.56

Pfizer Exclusive Countries\*

Americas

*Ecuador*  
*Uruguay*

Africa/Middle East

*Algeria*  
*Egypt*  
*Israel*  
*Jordan*  
*Kenya*  
*Kuwait*  
*Lebanon*  
*Morocco*  
*Nigeria*  
*Oman/Qatar*  
*Sudan*  
*Tunisia*  
*United Arab Emirates*  
*Yemen*

Europe

*Austria*  
*Belarus*  
*Bulgaria*  
*Croatia*  
*Estonia*  
*Kazakhstan*  
*Latvia*  
*Lithuania*  
*Romania*  
*Slovenia*  
*Uzbekistan*  
*FR Yugoslavia*

Asia/Pacific

*Vietnam*

*\* Subject to conversion  
pursuant to section 2.3 of  
the Global Agreement*

02/02/1998

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**EXHIBIT 1.64 - SEARLE Exclusive Countries**

**EXHIBIT 1.64**

**Searle Exclusive Countries**

**Asia/Pacific**

*New Zealand*

**Middle East/Africa**

*Cyprus*

02/02/1998 04/20/1998

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**EXHIBIT 2.1 - International Co-Promotion  
Heads of Agreement**

16 February 1998

EXHIBIT 2.1

HEADS OF AGREEMENT

INTERNATIONAL COLLABORATION AGREEMENTS

(Celecoxib and Second Generation)

Pursuant to the Global Agreement, the parties shall enter into an International Collaboration Agreement (Celecoxib) ("International Collaboration Agreement") and an International Collaboration Agreement (Second Generation) ("International Second Generation Collaboration Agreement") (collectively "International Collaboration Agreements"), the terms of which shall be essentially the same as the terms of the U.S. Collaboration Agreement (Celecoxib) and the U.S. Collaboration Agreement (Second Generation), respectively (collectively the "U.S. Agreements") and reflecting the following terms and conditions:

A. Provisions Relating to both International Collaboration Agreements.

1. Parties. The parties may enter into the International Collaboration Agreements on their own behalf and on behalf of an Affiliate to be named or organized.
  
2. Definitions. Defined terms used therein shall have the same meaning as in the Global Agreement.

3. Countries. The Co-Promotion, Co-Marketing, Searle Exclusive Countries, and PFIZER Exclusive Countries are defined in the Global Agreement. In order for either party to be eligible as a co-promotion party in any Country, such party must be able to demonstrate the following:

- the ability to provide from internal/external sources 70% of their share of agreed-upon details specified in the Co-Promotion Plan for such Country; and
- the ability to provide in such Country necessary sales, marketing and product services as are customary.

4. Brazil. In the event Pharmacia/Upjohn or any other third party has any co-promotion, license, marketing or other rights in Brazil to the Product and/or the Second Generation Product, SEARLE would agree that financial adjustments would be made so that PFIZER's economic return for Brazil is not adversely impacted (i.e., overall financial position of PFIZER for Brazil would be equal to that which would result under the exclusive co-promotion scenario).

5. France. SEARLE will co-promote the Product in France either exclusively with PFIZER or together with PFIZER and a second co-promotion partner to be named by SEARLE. SEARLE will decide which arrangement will apply; provided, in any event, PFIZER will be a co-promotion partner. If there are two co-promotion partners in France (in addition to SEARLE promotion), PFIZER would only be responsible for one-third of the Promotion Expenses and Development Costs allocable to France and the percentage share of Net Sales to be received by PFIZER, following the payment mechanism set forth in Section 6.3 of the U.S. Collaboration Agreement, shall be reduced with respect to France in proportion to the foregoing reduction in expenses and costs.

6. Contract Sales Force. Either party shall be allowed to use Sales Representatives who are not their respective employees without any restriction on the physicians which such Sales Representatives may detail.

7. Inventory. Minimum inventory requirements for the Co-Promotion Countries, if any, shall be negotiated by the parties.

8. Payment Currency. Notwithstanding Section 4.5 of the Global Agreement, SEARLE is willing to discuss with PFIZER alternatives with respect to all payments to be made under the International Agreements, provided that such alternatives do not result in any additional costs or risks to SEARLE.

9. Daily Sales Reports. Daily gross sales reporting requirements will not apply to these agreements.

10. Term. The International Collaboration Agreement shall be effective as of the Effective Date and shall continue in force in each Country until the expiration of the Co-Promotion Term in that Country or until sooner terminated or extended as provided herein. If at the end of the Co-Promotion Term under the U.S. Collaboration Agreement, the U.S. Collaboration Agreement (Second Generation) remains in full force and effect, and Monsanto causes SEARLE, upon PFIZER's request, to negotiate with PFIZER an extension to the term of the U.S. Collaboration Agreement, the parties shall negotiate in good faith (such negotiations to be for a reasonable period not extending beyond one Year prior to the end of the Co-Promotion Term under the U.S. Collaboration Agreement), an extension of the term of the International Collaboration Agreement (if so requested by PFIZER, on a Country-by-Country basis).

11. Governing Law/Dispute Resolution. New York law shall govern the International Collaboration Agreements. The mechanisms for dispute resolution shall be as set forth in the Global Agreement, including the governance committee structure.

B. Provisions Relating to the International Collaboration Agreement only.

1. International Milestones \$(Millions)

Execution of definitive International \$15

Collaboration Agreement,

International Second Generation

Collaboration Agreement, International

License Agreement, and

International Second Generation License

Agreement

EMEA filing with validation for 60

the Product, or if not applicable,

upon similar filing with validation in two (2) Major

European Countries

Performance Milestones (based on Net Sales in Europe)

<u>Year 1</u> (Millions)		
First Year Sales	Cumulative Net Sales	Milestones
\$200	—	\$15
<u>Year 2</u> (Millions)		
Second Year Sales	Cumulative Net Sales	Milestones
\$250	\$450	\$15
<u>Year 3</u> (Millions)		
Third Year Sales	Cumulative Net Sales	Milestones
\$350	\$800	\$30

"Year" for purposes of the Performance Milestones shall be determined for Europe as set forth in Section 4.4 of the Global Agreement.

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**EXHIBIT 2.2 - International License Heads of Agreement**

16 February 1998

EXHIBIT 2.2

HEADS OF AGREEMENT

INTERNATIONAL LICENSE AGREEMENTS

(Celecoxib and Second Generation)

Pursuant to the Global Agreement, the parties shall negotiate and execute an International License Agreement (Celecoxib) (the "International License Agreement") and an International License Agreement (Second Generation) (the "Second Generation License Agreement") (collectively, the "License Agreements"), the terms of which shall include:

1. Definitions. The definitions provision shall define the terms used in the International License Agreements, which, to the extent possible, shall follow the definitions of the Global Agreement. Capitalized terms used herein shall have the meaning set forth in the Global Agreement.
  
2. Licenses. Subject to the conversion rights in the Global Agreement, SEARLE shall grant to PFIZER the following licenses:

- An exclusive license to use and sell Product and Second Generation Product under separate Trademarks for each of the Product and Second Generation Product in each PFIZER Exclusive Country and an exclusive license under the Patent Rights and Know-How to use and sell Product and Second Generation Product in each PFIZER Exclusive Country.
- A semi-exclusive license under a Trademark, the Patent Rights, and Know-How to use and sell Product and Second Generation Product in each Co-Marketing Country.

3. Trademarks.

- To the extent possible, a single Trademark for each of PFIZER and SEARLE shall be selected by SEARLE under which each of the Product and Second Generation Product is promoted and sold in the License Territory. To the extent possible, such Trademarks will be owned by SEARLE.
- If PFIZER is required by Law to own any Trademarks, it may do so, provided that it utilizes only one Trademark for each of the Product and Second Generation Product in any one Country. Further, upon termination of the License Agreements, PFIZER shall transfer any and all rights in such Trademarks to SEARLE. PFIZER shall have the right to utilize such

Trademarks solely in connection with its activities under the License Agreements.

4. Technical Information. PFIZER shall, to the extent necessary, have access to all material Know-How during the term of the License Agreements.

5. Co-Marketing. To the extent consistent with applicable Law, the CCC for each Co-Marketing Country shall prepare a Co-Marketing Plan (similar to the equivalent Co-Promotion Plan under the International Collaboration Agreements) on an annual basis, but each party shall separately determine and be responsible for its own marketing, promotion, detailing, distribution and sales of Product and Second Generation Product, consistent with the medical and scientific determinations made under the Global Agreement.

6. Special Considerations for Co-Marketing Countries

- Launches of both brands will be simultaneous.
- Searle will retain the right to use the global Trademark and related promotional materials. Pfizer shall use an alternate Trademark.
- Development Costs for studies which are part of global development shall be split evenly between the parties.

- As both parties within a Co-Marketing Country cannot use identical sales and promotional materials, both companies must develop their own promotional materials based on the core clinical data and global strategy.
- Searle shall provide to Pfizer access to a reasonable quantity of samples (in bulk capsule form) in each Country in the License Territory as agreed by the parties. It is expected that allocation of samples between the co-marketing parties shall be equal if the number of details to be conducted by such parties pursuant to the Co-Marketing Plan are equal.

7. Pfizer Exclusive Countries. With respect to PFIZER Exclusive Countries:

- PFIZER shall each Year prepare a marketing plan.
- PFIZER shall be responsible for its own marketing, promotion, detailing, distribution and sales of Product and Second Generation Product, consistent with the applicable marketing plan.
- PFIZER will have access to all promotional materials developed jointly by the parties.
- PFIZER may use the global Trademark and will retain, rights to use it upon conversion, from an Exclusive Country to a Co-Marketing Country but only for the term of the applicable agreement.

8. Cooperation and Information Exchange. The parties shall cooperate with each other and use reasonable efforts to maximize Net Sales of the Product and Second Generation Product. For this purpose, the parties shall share information as appropriate and to the extent permitted by applicable Law.

9. Regulatory matters. Subject to review by the parties as to practicality of implementation, it is expected that:

- To the extent permitted by applicable Law, SEARLE shall have the final authority for all matters relating to the development of the Product and Second Generation Product, including the filing of the Product or Second Generation Product as a new drug in the Co-Marketing Countries and the PFIZER Exclusive Countries.
- To the extent required by applicable Law, PFIZER shall obtain the appropriate regulatory approvals for the Product and Second Generation Product to market, distribute and sell the Product and Second Generation Product in PFIZER Exclusive Countries and, on behalf of PFIZER, in Co-Marketing Countries.

- Prior to filing the appropriate new drug applications or other communication with Governmental Authorities, PFIZER shall submit copies of such applications to SEARLE for its review, comments, and approval.
- SEARLE shall use all reasonable efforts to provide to PFIZER any all necessary information and documentation for the above-described regulatory filings with Governmental Authorities.
- Upon termination of PFIZER's rights with respect to a Co-Marketing Country or PFIZER Exclusive Country, PFIZER shall assign to SEARLE, a SEARLE Affiliate, or a third party designated by SEARLE, any and all marketing authorizations and approvals (including pricing approvals) relating to the Product and/or Second Generation Product in that Country.

10.1 Supply of Product.

- Subject to the terms and conditions in the Global Agreement, SEARLE shall use all reasonable efforts to supply Product and/or Second Generation Product in bulk capsule form, and PFIZER shall purchase from SEARLE such Product and Second Generation Product.
- Minimum inventory level requirements, if any, shall be negotiated by the parties.

10.2 Specifications.

- SEARLE shall supply bulk Product and Second Generation Product manufactured, packaged and supplied in accordance with applicable Laws and according to the specifications notified to PFIZER from time to time.

10.3 Forecasts. PFIZER shall provide SEARLE with reasonable advance forecasts of PFIZER's bulk Product and Second Generation Product requirements.

10.4 Prices and Payment. The Price for bulk capsules of Product and Second Generation Product shall be thirty percent (30%) of PFIZER's Net Sales, subject to a minimum price to be negotiated by the parties. Arrangements concerning payment for such purchase price and for packaging of finished product shall be negotiated by the parties. Notwithstanding Section 4.5 of the Global Agreement, SEARLE is willing to discuss with PFIZER alternatives with respect to all payments to be made under the International Agreements, provided that such alternatives do not result in any additional costs or risks to SEARLE.

11. Information Concerning the Product.

- PFIZER shall not make any public statements in connection with the Product or Second Generation Product or its activities under the International License Agreements that are inconsistent with any applicable marketing authorization.